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Case No: CL-2022-000676

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
OF ENGLAND AND WALES
KING'S BENCH DIVISION
COMMERCIAL COURT

Rolls Building
Fetter Lane
London
EC4A 1NL

Date: 1 October 2025

Before:

MRS JUSTICE COCKERILL DBE

- -

Between:

THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Claimant

- and -

PPE MEDPRO LIMITED

Defendant

- -
- -

Paul Stanley KC, Tiran Nersessian, Albert Sampson and Josh O'Neill (instructed by **Government Legal Department**) for the **Claimant**
Charles Samek KC, Ashley Cukier and Bláthnaid Breslin (instructed by **Grosvenor Law Limited**) for the **Defendant**

Hearing date: 11,12,16,17,18,24,25,26,30 June, 8,9,10 July 2025

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JUDGMENT

This judgment was handed down by the court in person and by circulation to the parties' representatives by email and released to The National Archives. The date and time for hand-down is deemed to be 1 October 2025 at 10:30am.

Mrs Justice Cockerill:

INTRODUCTION

1. In mid May 2020 England was still in the first phase of the COVID lockdown, though COVID numbers and deaths were dropping. Discussions were ongoing as to the easing of lockdown measures. But many people were still getting very ill with COVID; and the Department of Health and Social Care ("DHSC") was looking to maintain supplies of appropriate medical devices – such as sterile gowns, non-sterile ("isolation") gowns, masks and gloves.

2. Against this background the Defendant ("Medpro"), a relatively new company which had access to the so-called "VIP lane" of PPE supply, offered to source and supply sterile gowns. After discussion, during the course of which one of the relevant teams in DHSC said that the submission in respect of the gowns was "technically approved", a draft contract was sent out and was later concluded.

3. The gowns were delivered ex works in China between July and early September. DHSC paid a few pence less than £122 million for them.

4. They arrived in tranches between mid August and mid October. They were not inspected until some time after they had arrived in the UK. On inspection it was concluded that the gowns were not appropriately marked and the DHSC was not satisfied that the gowns were contractually compliant. Just before Christmas 2020 DHSC served a notice rejecting the goods and seeking its money back. Still later a selection of gowns was tested, and it was found that a number of them were not sterile.

5. Overall DHSC claims the following (capped under the contract at £128,099,180):

    a. Repayment of the Contract price: £121,999,219.20;

    b. Storage Costs of £8,648,691 for the period between February 2021 and June 2024.

6. That claim raises issues of the terms of the contract, representations said to have been made at the time, and (perhaps more interestingly) of the nature of sterility, statistical probability and the significance of organisms isolated from a deep trench in the Pacific. Then there are issues as to the right to reject the goods, and whether DHSC can claim the full value of the gowns in damages.

7. Those issues and issues as to the extent of the claim are considered further below under broad headings as follows:

    a. Sterility 101: an introduction to sterility and medical device law

    b. Factual background

    c. The Contractual Claim

    d. Estoppel and related concepts

e. Remedies

f. The Counterclaim.

STERILITY 101: AN INTRODUCTION TO STERILITY AND MEDICAL DEVICE LAW

8. An essential part of the background to this case is the concept of sterility. On one level this is a sale of goods case, like many others. Goods were bought and delivered. The buyer claims they are not of satisfactory quality and seeks to get its money back. That is the way this case was originally pleaded. It was advanced on the basis of the following propositions, familiar in their outlines to all commercial lawyers:

   a. You agreed to sell us sterile gowns.

   b. We paid and took delivery of gowns.

   c. We tested the gowns and they were not sterile.

   d. Therefore they were not of satisfactory quality and we want our money back.

9. But sterile gowns are not bulk grain cargoes. The experts are agreed that sterility cannot be adequately tested for and that in practical terms it is not useful to contract by reference to sterility *per se*, essentially because (i) sterility (freedom from/absence of any viable micro-organism) is an absolute state – Mr Atchia, Medpro's expert says "*there is no half way house*" (ii) there is no sensible way of testing this without destroying the sterility of the item in question.

10. If sterility is an absolute state how does the market stipulate for and assess sterility? The experts are agreed that this is done by reference to something called a "Sterility Assurance Level" ("SAL"). SAL represents the "*theoretical probability*" of sterility in relation to each medical device, namely the theoretical probability of there being (or of detecting, which in practice comes to the same thing), after sterilisation, a viable micro-organism on the device. The reference to assurance is a logical concomitant of this – because the theoretical probability of a microorganism is so low, the confidence or assurance level can be high. The user can be in mathematical terms next door to sure that the item is sterile.

11. In this case it is common ground that the contractually stipulated SAL for the gowns was 10^{-6}.

12. That presents the question as to how SAL is achieved. That question is at least typically answered by a fairly complex web of standards. To understand even the factual background to this case and the outcome it is necessary to appreciate the following (some of which is repeated later in the judgment as relevant).

13. Any assessment of SAL is based on the demonstration of the absence of growth of any viable micro-organism following a sterility test. Industries that deal in questions of sterility will generally use official standards to set parameters for how this is to be done and what assurance level is needed. In the UK, for instance,

these are standards published by the British Standards Institution and designated by the Government. Some of these standards may be non-British standards, for example, EU standards or International Standardisation Organisation ("ISO") standards.

14. Some standards incorporate microbial inactivation data and have been developed to measure, control and demonstrate the efficiency of a sterilisation process. Some standards deal with other aspects of a process to reach the same goal – demonstration of the absence of growth of any viable micro-organism following a sterility test. Some standards deal with different ways of sterilising. In this case the method used was ionising radiation and the experts in this case agreed "*ionising-radiation was a suitable- and perhaps the ideal - method to sterilise*" medical gowns of the sort in question.

ISO 11137: Requirements of a Sterilisation Process

15. The main international standard which is relevant for current purposes is ISO 11137. That is a standard which has a fairly long history. It comes in two major parts:

    a. Part 1: Deals with the requirements for development, validation, and routine control of a sterilisation process for medical devices. In particular it covers:

        i) Definitions, Quality Management system elements, Sterilising agent issues, Process and equipment, process definition, validation (including review and approval of validation), monitoring and control and maintaining process effectiveness;

        ii) It defines:

            1) SAL as "*probability of a single viable microorganism occurring on an item after sterilization*";

            2) Sterilisation as "*validated process used to render product free from viable microorganisms*";

            3) Sterilisation dose as "*minimum dose needed to achieve the specified requirements for sterility*";

            4) Validation as *"documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications".*

        iii) It sets out requirements for each of the stages described above

> "that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence,

> that there is a low level of probability of there being a viable microorganism present on product after sterilization."

b. Part 2: Deals with establishing a sterilisation dose of radiation for health care products. This document is 85 pages long. It includes guidance as to:

   i) how to select and test a product to establish a sterilisation dose,

   ii) how then to establish the proper dose.

   iii) methods to establish the right dose (using bioburden information) and to audit the dose.

16. One aspect which came sharply into focus in the evidence was a section of part 7 of the standard on how to obtain a verification dose. This provided as follows (and was to be preceded by establishing an average bioburden of the product in question):

> "Obtain the dose for an SAL of 10^{-2} from Table 5 using one of the following as the average bioburden:
>
> a) if a batch average bioburden is two or more times greater than the overall average bioburden, use the highest batch average bioburden, or
>
> b) if each of the batch average bioburdens is less than two times the overall average bioburden, use the overall average bioburden.
>
> If the average bioburden is not given in Table 5, use the closest tabulated value greater than the average bioburden.
>
> Designate this dose as the verification dose."

17. Table 5, which the reader is spared, is entitled "*Radiation dose (kGy) required to achieve a given SAL for an average bioburden greater than or equal to 1,0…"*. It has columns with average bioburden from 1 to 1,000,000, and columns for SAL 10-2, 10-3, 10-4, 10-5 and 10-6.

18. After that the standard envisaged:

   a. Testing 100 samples at this dose, and checking them. It is readily apparent how this acts as a functional proxy for testing actual product post delivery.

   b. Obtaining a sterilisation dose by entering the table at the tabulated value equal to the average bioburden and reading the dose necessary to achieve the desired SAL.

19. In other words, the process envisages testing samples before irradiation of products is commenced in order to get the dose right and for the dose set to be geared to bioburden.

20. The standard also has two further parts, not really in focus here, but of some interest. Part 3 provides guidance on dosimetric (measurement of the absorbed radiation dose) aspects during development, validation, and control. Part 4 was only issued in 2020. It offers additional guidance on process control for sterilisation using ionizing radiation; i.e. how to ensure that the process, once established, is robust.

21. That ISO standard appears to be widely used internationally. But how it is used depends on the relevant local regime. Hence the reference in ISO11137 to "*specified requirements for sterility*".

22. The ISO standard Part 1 notes at 1.2.1 that "*This part of ISO 11137 does not detail specified requirements for designating a medical device as sterile. NOTE Attention is drawn to regional and national requirements for designating medical devices as "sterile". See, for example, EN 556-1 or ANSI/AAMI ST67.*"

Sterility level: EN 556

23. Here the relevant law at the time was provided by the EU Directives and regulations. For EU and UK purposes the relevant standard for sterility is EN 556-1: 2001. This provides that

> "4.1 For a terminally-sterilized medical device to be designated "STERILE", the theoretical probability of there being a viable micro-organism present on/in the device shall be equal to or less than 1 : 10-6…4.2 Compliance shall be shown by the manufacturer or supplier through provision of documentation and records which demonstrate that the devices have been subjected to a validated sterilization process fulfilling 4.1..
>
> The documentation and records shall be retained as specified in EN ISO 13485:2000, 4.5 and 4.16 or EN ISO 13488:2000,"

Medical devices: MD Directive and MDR 2002

24. Equally ISO 11137 does not specify any particular quality management system to control all stages of production of medical devices.

25. The gowns were medical devices regulated by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (the "MD Directive"), and the Medical Devices Regulations 2002 ("MDR 2002").

26. These provided the following structure:

    a. The MD Directive put in place a structure dividing medical devices into categories, of which Category I and IIa are relevant here. The first, Category I, is the most basic level where manufacturers could essentially self certify. Category IIa was a category where the risk profile required higher quality assurance, including *"the intervention of a notify body at the production stage"* – and where compliance could not be achieved without it.

b. Regulation 8 MDR 2002 provided that, subject to Regulation 12, no person would place on the market, put into service, or supply a medical device unless it met the essential requirements set out in Annex I to the MD Directive, which provided (section 8.4) that the device must be manufactured and sterilised by an appropriate, validated method;

c. Regulation 13 referred to Annex V of the MD Directive, which prescribes a system for approval of the quality assurance system for the process for production of relevant medical devices. It involves the provision of information as to the detailed operation of the system, inspection of the operation of the system and the production of a declaration of conformity with the process;

d. Regulation 10 MDR 2002 provided that no person would place on the market, put into service or supply a sterile medical device unless the device or its sterile pack, sales packaging or instructions bore a "CE mark" that was accompanied by a relevant "notified body number".

   i) A CE mark was a concept introduced by EC Regulation 765-2008 which covered accreditation of processes. It specifically provided for CE marking "*indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense."* More specifically *"By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing*."

   ii) Pursuant to Regulation 13 MDR 2002, a CE mark could only be applied to a sterile medical device if three conditions were met:

      1) the manufacturer or its authorised representative must have fulfilled the obligations imposed by Annex VII to the MD Directive (reg. 13(1)(a));

      2) the manufacturer or its authorised representative must have issued a declaration of conformity in respect of the relevant medical device in accordance with Annex VII to the MD Directive (reg. 13(1)(b)); and

      3) the manufacturer or its authorised representative must have ensured that the device met the requirements of the MD Directive (reg. 13(1)(c)).

   iii) A "notified body" was a supervising body approved by a local jurisdiction which might be required to certify the processes at different stages. So for particularly high risk devices notified body certification needed to cover design and manufacture; for medium risk it was required for manufacture only, whereas for lower risk (non-sterile) items no notified body was necessary – manufacturers could self certify. For sterilised products however the notified body needed to certify the

procedure leading to the obtaining of sterility until the sterile package is opened.

Other relevant standards

27. There are a number of other standards which come into the picture during the course of this case.

28. The most important is not, strictly speaking, a sterility standard at all. It is EN 13795-1. That standard is entitled: "*Surgical clothing and drapes – Requirements and test methods"* and covers performance in matters such as resistance to penetration of liquids, the degree of mechanical stress on the materials and electrostatic performance.

29. Linked to this standard are standards such as EN 17141 relating to clean controlled environments in manufacturing areas where medical devices are produced.

30. Also occurring in the references within the material are:

    a. EN ISO 13485 – "*Quality systems — Medical devices — Particular requirements for the application of EN/ISO 9001"* ([Model for quality assurance in design/development, production, installation and servicing]). These are the foundational standards on top of which ISO 11137 sits;

    b. EN 550, 552 and 554 which deal with various other types of sterilisation procedures;

    c. EN 1174 - sterilization of medical devices — Estimation of the population of micro-organisms on product.

Summary

31. For current purposes, key points, as set out in these detailed standards, are:

    a. ISO 11137 is a technical overarching standard for the process for sterilising medical devices. In its different parts it looks at the whole process – planning, calibration and execution, but does not stipulate a particular SAL;

    b. MD Directive and MDR 2002 covers a very wide range of medical devices, sterile and not sterile. As to CE marking of gowns specifically:

        i) Sterile gowns, as a sterile product, are required to have a CE mark accompanied by a notified body number;

        ii) Non-sterile (isolation) gowns require only a CE mark without a notify body number.

    c. EN 556 sets out the standard EU requirement of SAL for sterile devices and contemplates a quality management system in line with the other EU standards.

FACTUAL BACKGROUND

The COVID backdrop

32. By March 2020, Covid-19 was spreading throughout the UK. On 23 March 2020, Boris Johnson, then the Prime Minister of the United Kingdom, announced a national lockdown, by which people were ordered to stay at home save for very limited circumstances, including for medical purposes, to travel to work where the work could not be performed from home, infrequent shopping, and for one form of exercise per day.

33. The Government needed to procure supplies that could be used by the NHS to enable staff to care for patients while protecting themselves and their patients against the risk of infection, as the disease was highly infectious.

The PPE Cell

34. Various programmes were urgently put into place by the Government in order to support its response to Covid-19. One of these was the formation of the Government's "PPE Cell", a specialist unit reporting to DHSC which was tasked with the operation of a parallel supply chain for the procurement of personal protective equipment ("PPE") for the NHS. In other words, it operated distinctly from the extant NHS procurement supply chain.

35. The PPE Cell was formed over the weekend of 20 and 21 March 2020. It comprised a team of commercial professionals, enlisted from a range of government departments and functions (including but not limited to the NHS, industry, and the armed forces), who were tasked with the operation of the parallel supply chain for PPE.

36. A portal was established on the Gov.uk website at "*https://www.gov.uk/coronavirus-support-from-business*", through which offers to supply products and services related to PPE and medical devices could be made (the "PPE Portal").

37. At the times material to these proceedings, the PPE Cell included the "Opportunities Team", the "Technical Assurance Team", the "Closing Team" and the "Deals Committee". These were the teams that reviewed the Defendant's offer to supply sterile surgical gowns in this case. Potentially viable offers for PPE were processed first by the Opportunities Team, then Technical and Closing. Once an offer or proposed contract had successfully passed through all these stages the ultimate authority to approve a PPE Cell procurement contract lay with the Accounting Officers who would take into account, among other matters, the Closing Team's recommendations.

38. The Opportunities Team was responsible for contacting a potential supplier, discussing the scope of their offer, gaining a "general perspective" on the "credibility" of the offer, and deciding "*whether there was sufficient information to send [the offer] through to the Technical Assurance Team*". They were not technical specialists; they were largely seconded from the Department for Education with some from the Ministry of Defence. They had a basic commercial

skillset – enough to deal with prospective suppliers with some understanding of what would be needed for technical approval, to ensure that submissions usually had the right documents.

39. The Opportunities Team included a team referred to as the "High Priority Lane" (the "HPL"), which was set up in late March 2020 – also referred to in press coverage as "the VIP lane". The purpose of the HPL was to manage the large number of referrals that were being made outside the PPE Portal by senior officials. It was reserved for referrals from MPs, ministers and senior officials, including those in the NHS. The HPL team would get in touch with those potential suppliers and find out further information from them about their business, their products and offers (which was the same process as that followed by the wider Opportunities Team). Potentially viable offers that came into the PPE Cell through the HPL were also reviewed by the Technical Assurance Team, the Closing Team and the Deals Committee, and had to be approved by the Accounting Officers. Guidance issued to the Opportunities Team produced on 6.5.20 included a "Checklist of required information". That required the Opportunities Team to check for each of the product types offered:

> "• Whether they are CE marked
>
> • Any other certifications they hold
>
> • Confirmation that they meet the specifications supplied by NHS."

40. The Guidance (being "reference only") instructed Opportunity Team members on "*How to help progress a good quality submission to the Tech Assurance team*". This entailed submitting a full set of documentation from the supplier to Technical, and was intended to help the Opportunities Team (not technical specialists themselves) understand what Technical will be looking to achieve by reviewing the documentation. The table also stated which documents were required (R) or preferred (P).

41. According to the table:

    a. The Declaration of Conformity, Technical would be looking for "*Manufacturer confirmation of the standard the product is conforming to", which was "[r]equired for all products*";

    b. The document on "Manufacturers certification", Technical would be looking for "*[c]onformance to required EN specification by a Notified Body (NB)", which was "[r]equired for all PPE submissions (NB)*";

    c. For documents relating to "*Confirmation of specification of sterilisation – CE certification required*", it stated that Technical was looking for "*Accredited to ISO EN 11135 (Ethylene Oxide) or ISO EN 11137 (Gamma Radiation)*" and "Packaging marking to EN 15223". This was stated to be a "Requirement" for "sterile products (NB)".

42. If, upon the upward referral of an offer, Technical sought additional information, the Opportunities Team would relay this to the relevant supplier, and the supplier

could then provide the information (if available) to the Opportunities Team, who would upload the information to the online portal called "Mendix" directly for onward review. Mendix was where "*all the submission documents were saved*" and was where the PPE Cell "would record decisions" in relation to PPE offers.

43. In his evidence to the UK Covid-19 Inquiry, DHSC's Accounting Officer Mr Williams described that the role and responsibility of Technical (as he puts it, "technical review and technical assurance") was to be clear whether a product did or did not meet technical specifications. If an offer was "accepted", Technical would indicate this in Mendix. "Accepted" meant that the product appeared "on the documentation submitted" to "*be capable of meeting the required standards in the specification*".

44. Members of Technical "*were seconded from the MoD*" and "*while they might not have worked on PPE or medical devices, many as a part of their role in the MoD were involved in procuring equipment that had to meet technical standards so they had experience in conducting technical appraisals and reviewing documentation against standards*". The role and responsibility of Technical included (i) checking whether a product appeared to have appropriate CE marks and certificates; (ii) verifying the documentation provided by a potential supplier against the regulatory requirements and specification of the product that was being offered; (iii) checking "*technical documentation from the potential supplier that demonstrated compliance with the published requirements*"; and (iv) comparing the documentation provided by the potential supplier to the list of NHS Technical requirements to see if it did or did not meet the requirements. Thereafter, they would make a decision whether to accept the offer, put it on hold or reject it. An offer would be immediately rejected by Technical "*if documents were obviously missing*".

45. Members of Technical could also, "*where there was value*" in an offer, "*consider an equivalent technical solution instead of losing the offer*". If a submission by a supplier had the potential to meet the requirements of an equivalent technical solution, it would be discussed "*at one of the daily technical assurance meetings to seek the wider technical assurance team's views and to make a decision*".

46. Once an offer passed through Technical, Closing would negotiate the commercial terms and agreement to contractual terms and conditions before the order could be placed. Closing had to prepare a submissions "pack" for the Deals Committee (also referred to as the PPE Clearance Board), which was made up of senior personnel and chaired by Mr Hall from the Cabinet Office, and which approved offers. There would be a "peer review" before Closing could submit the "pack".

47. If a deal passed the Deals Committee, it had to go through DHSC Finance, and then to the Accounting Officer for sign-off. For PPE related procurement, this was David Williams, Director General of the Finance Group Operations and Second Permanent Secretary at the DHSC. For contracts over £100m, Mr Williams had to personally approve DHSC's entry into contracts (Williams 1, paragraph 4). Following approval by the Accounting Officer, a Purchase Order would be issued, and the contract would be executed.

The Recommendation

48. On 13 March 2020 the European Commission issued a Recommendation (EU) 2020/403 (the "Recommendation"), on which Medpro relies heavily. This provided as follows:

    a. Recital (2) "*Bearing in mind that the health and safety of the EU citizens is of upmost priority, it is of paramount importance to ensure that the most appropriate PPE and medical devices ensuring adequate protection are swiftly made available to those who need it most*";

    b. Recital (14) "*In accordance with Article 11 of Directive 93/42/EEC … in order to place medical devices on the market, manufacturers shall carry out the applicable conformity assessment procedures and, where compliance with the applicable essential requirements or general safety and performance requirements has been demonstrated by the appropriate procedure, affix the CE marking. Derogations from conformity assessment procedures may be authorised by Member States, on duly justified request, for the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices the use of which is in the interest of protection of health.*"

    c. Recommendation [8] "*PPE or medical devices not bearing the CE marking could also be assessed and part of a purchase organised by the relevant Member State authorities provided that is ensured that such products are only available for the healthcare workers for the duration of the current health crisis and that they are not entering the regular distribution channels and made available to other users*."

49. As DHSC noted, the Recommendation had no legal force. It did however evidence an atmosphere in which governmental departments were open to measured departures from the precise regulatory requirements.

The Essential Technical Requirements Document ("ETRD")

50. On 23 May 2020, the Government published a document setting out "*Essential technical requirements for gowns, gloves, masks, respirators, eye protection and coveralls where no CE mark has been obtained or where an alternative use is proposed of an existing CE marked product*". The document was prepared by the MHRA and the HSE, fairly obviously in the light of the Recommendation.It is relied on by Medpro as highly relevant to contractual construction.

51. The ETRD set out the approach that the MHRA intended to take following the Commission Recommendation. It pointed out that:

    a. "*Normally, such products must meet requirements set out in the relevant legislation as listed above and hold a valid CE mark before being placed on the market or put into service. However, bearing in mind the health and safety is the upmost priority, it is of paramount importance to ensure that the most appropriate PPE and medical devices ensuring adequate protection are swiftly made available to those who need it most during the Covid-19 threat*."

b. "*Where market surveillance authorities find that PPE (Health and Safety Executive HSE) or medical devices (Medicines and Healthcare products Regulatory Agency MHRA) ensure an adequate level of health and safety in accordance with the essential requirements laid down in Regulation (EU) 2016/425 or the requirements of Directive 93/42/EEC even though the conformity assessment procedures, including the affixing of CE marking, have not been fully finalised according to the harmonised rules they may authorise the making available of these products for supply to frontline healthcare if sourced by Government and with the caveat that they are not distributed more widely. MHRA call this exemption from devices regulation a derogation.*"

52. It then explained key criteria thus:

> "Before such COVID-19 related products are purchased by or donated to the Government/NHS to be used by NHS healthcare workers, it must meet all the following criteria to ensure they are fit for the purpose intended, will work in line with stated performance and have been assessed as such.
>
> The products are therefore designed and manufactured in accordance with either:
>
> a) a relevant harmonised European standard, or
>
> b) any of the standards referred to in the WHO guidelines or,
>
> c) any other non-EU standard or technical solution, provided that the specific solution ensures that the product complies with the applicable essential health and safety requirements"

53. Its purpose was then set out: "*This guidance sets out the essential technical and labelling requirements for these products to support meeting the criteria specified above*." It, however, stated that "*Meeting these requirements does not guarantee clearance of an application by MHRA or HSE, as relevant. Robust scrutiny by MHRA or HSE of the information in your application will take place before a decision is made to allow you to supply to the UK*."

54. Table 1 of the ETRD then set out the "essential requirements" for medical devices, where "must" defined essential requirements and "should" defined requirements which were highly desirable but where consideration could be given to omitting the requirement to speed up provision. It listed a number of items - surgical face masks, gloves, and the like.

55. Under "sterile gowns" the table included the requirement:

> "Must be validated as sterile with Sterility Assurance Level (SAL) of 10^{-6}"

The parties are in agreement that this was a requirement of the supply of gowns in question here.

56. More controversial was the final column (headed "*relevant standards for design and performance*") which stated:

> "BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods
>
> or
>
> AAMI PB70 (all levels accepted or equivalent)
>
> and BS EN 556-1:2001 for terminally sterilised medical devices (where applicable) or equivalent technical solutions"

AAMI PB 70 is the approximate US equivalent of ES 13795. As will be apparent from the preceding section this notation indicated a requirement for compliance with a construction/performance standard and a sterility requirement.

Precontractual Negotiations

Opportunities and Technical

57. Medpro was incorporated on 12 May 2020 and referred to the HPL by Baroness Mone the same day. Also that day, Richard James from the Opportunities Team of the PPE Cell took over liaison with Medpro from a colleague. Mr James was a commercial specialist with a background in procurement largely in the private sector.

58. In an email to Baroness Mone on 12 May, Mr James requested the contact details of Anthony Page, Director at Medpro. It was he who was at all times negotiating on behalf of Medpro (although Mr James' evidence is that Baroness Mone remained active throughout). A telephone call between the two followed, after which Baroness Mone emailed Mr James with the contact details, CC-ing Mr Page.

59. Mr James replied to both, requesting to speak with Mr Page the next day, on 13 May 2020. In that same email, he listed the priority for masks, gowns and aprons, inserting a link to the required specifications: https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe . Mr James stated that "*we do undertake steps to conduct both commercial/financial and technical due diligence before placing any orders and I can talk you through what we may require in this regard when we speak. Please note as well, that this applies to the original equipment manufacturers as well and we will look to confirm the bona fides of overseas manufacturers as well. However, for offers of substantial volumes where technical certification is of a high quality this process is highly accelerated*".

60. Medpro's initial offer was made on 13 May 2020, and related to 210m Type IIR face masks to DHSC. Following a call on 13 May (which had been facilitated by Baroness Mone on the previous day), Mr James sent an email to Mr Page, asking for full company details of Medpro, "*in order to get the ball rolling… Also if you*

are interested in adding offers for gowns and gloves, please confirm the quantities and indicative pricing and I can add these into the offering."

61. Details on non-sterile gowns were duly sent. However on 17 May 2020, Mr James informed Mr Page that the details forwarded by Medpro on the offer of non-sterile gowns did not meet the technical standards, but he invited offers for other priority items such as goggles, gloves and aprons that meet the specifications.

62. Mr Page replied: "*As you know there are a lot of traders out in the market and we are hearing a lot of horrible stories. We would love to work with the NHS so could you please explain more on what we need to do. It would be good to know why we didn't pass your technical audit on the gowns, we have been supplying this quality to the Australian Government*". There were then some exchanges to clarify the standards on non-sterile gowns – in particular as to accreditation of the factory.

63. Some issues were raised internally at DHSC with the recent incorporation of Medpro and the potential for conflict of interest, given Baroness Mone's husband's involvement. However Medpro's willingness to contract on DHSC's standard terms was noted as a plus point.

64. An order for masks was placed and in the event a contract for those was concluded on 2 June 2020. This in the event was carried out without complaint by DHSC. However, the offer of non-sterile gowns petered out since the view was forming that there was no longer a need for such gowns. By 21 May Mr James was stating he was not "*aware only sterile gowns were being progressed*" and queried whether, since the gowns were non-sterile, he should "*stop completely or just slow down*". Mr Beard responded that they had been asked to stop as they had "enough".

65. By contrast, there was an identified need for sterile gowns. This must have been communicated to Medpro (Mr Page most likely) since on 21 May 2020 he sent Mr James an email stating that Medpro could manufacture sterile gowns also, and asked for DHSC's specifications including the quantity of gowns needed. Mr James responded enclosing "the specs." This was a reference to the ETRD, which was sent with this email. It was therefore at this point that Medpro received the ETRD which was central to their analysis of the requirements. Mr James added he would check on the volumes required.

66. In an email of 2 June 2020, Mr Page told Mr James that "*With regards to Sterile Gowns we have managed to secure a production slot with our joint venture factory for 50 million units*". He added that the factory "*had been approved by the MHRA UK*" and that the production capacity was of 500,000 units per day and delivery could be on a weekly basis.

67. Mr James replied asking Mr Page to send "*all of the technical information through to confirm sterile status*." He asked also whether it was "*the same factory as previously*". That was a reference to the factory potentially identified as the manufacturer for the non-sterile gowns. Mr James added: "*If so, I can amend the submission, I think, and get it progressed quickly*."

68. On the same day, Mr Page replied with a link to a Dropbox folder containing comprehensive technical information relating to Medpro's sterile gowns offer.

69. Mr James responded that once he had the Declaration of Conformity, then "*I think the sterile gowns are good to go to Technical*."

70. On 3 June 2020 Mr James responded to queries from Mr Page that the offer of sterile gowns was "with the Technical Team". He added that: "*Current turnaround for Technical Appraisal is 24-48 hours, sometimes faster as they [i.e. sterile gowns] are priority items and we are doing well at clearing the backlog.*" In a later update he added that "*Just seen that Gowns have been allocated to a reviewer so hope that means a response today/tomorrow morning as it usually does.*"

71. On the same day a member of Technical made an entry in Mendix:

> "03/06/2020 Tech review: Not acceptable - return for further info. No declaration of conformity provided. No images of product or packaging provided."

72. On 4 June 2020 Mr James emailed Mr Page that Technical was concerned *inter alia* about "*Gowns No declaration of conformity provided. No images of product or packaging provided. Hope you can provide these by return and I'll resubmit.*"

73. On 5 June 2020, Mr Page sent Mr James a Dropbox folder link for the sterile gowns. He added "*Everything that you asked for is now in there.*" He added "*Do you think we will hear back today? We are desperately trying to hold this slot in our production.*" Mr James replied stating "*These are back in with the tech team. Their responses have been getting ever more rapid and, although they're working on skeleton staff over the weekend, I would hope to hear back shortly. I'll keep you posted and will be looking at the system regularly*."

74. The folder did contain photographs of gowns. However while the gowns had a CE mark, it was not a CE mark accompanied by a notified body number. As Mr Clarke was later to explain: "*If the product was a sterile product, if it was a Class 1 medical device, a Class 1 sterile, it should, when marked with the CE mark, be accompanied by the notified body number. … it is perfectly acceptable for some Class 1 devices, they only have to have the CE mark, they don't need to have the notified body number as well*".

75. On 7 June 2020, Mr James emailed Mr Page that he had "*submitted the gowns for approval and am hopeful this will come through shortly*."

76. On 8 June 2020, Mr Page chased Mr James again: *"Any news on the …, sterile gowns …? We are really trying our best to hold this production schedule for you"*. In fact, it seems that on 8 June 2020 – according to the evidence of Mr Clarke the head of the VIP team in Technical Assurance "*Graeme Wilkie [of Technical] reviewed the submission and put it on hold on 8 June 2020 due to a lack of certification for EN 556-1 regarding sterility.*" The Mendix entry stated: "*MOD QA Tech Review: 08/06/20 - Not Accepted, On Hold. No certification for BS EN 556-1-1:2001 for terminally sterilised aspects.*"

77. So, on 9 June 2020 Mr James emailed Mr Page that "*Sterile gowns response came back just now asking for certification for EN 556-1 for terminally sterilised aspects. Can you provide this and it will then go through.*"

78. However, it is apparent that Mr Page was unclear as to what was required and replied:

> "Hi Richard,
>
> Further to your email below are the certification requirements BS EN 13795 or AAMIPB70 and BS EN 556-1?
>
> We are checking with our factories who all have BS EN 13795.
>
> It is mentioned on the DHSC requirement to have the above or equivalent ISO standard.
>
> Can you please advise what ISO number is the equivalent?
>
> I would really appreciate if you could get back to me today as we are hoping to secure these orders."

79. It should be noted that this reply indicated that Mr Page had not understood the nature of sterility or the content of the relevant standards. BS 13795 was a standard which pertained to the manufacture of gowns (both sterile and non-sterile). It had nothing to do with SAL. The other standards were, as noted, sterility standards.

80. Mr James responded:

> "BS EN 556-1-1 is the standard for sterilisation and so is needed in addition to BS EN 13795 for sterile gowns. The wording in the specifications is "or equivalent technical solutions". This would require you to submit the details of what your manufacturer considers an equivalent technical solution and we would then apply for a derogation to BS EN 556-1-1. This would be a more lengthy process so I wouldn't recommend this course of action. Hope that helps."

81. Later that same day Mr Page emailed Mr James with "*the MHRA certificate of free sale for isolation surgical gowns from the relevant factory we submitted [in respect of the Wujiang Factory]. The factory is currently suppling [sic] the EU and the UK for sterile gowns. Can you please let me know ASAP".* Again Mr Page's lack of understanding is manifest: this certificate of free sale on its face related to *"isolation surgical gowns"* i.e. not sterile gowns. Not having received a reply, Mr Page emailed Mr James, querying: *"... do you require anything further? Do you think we will get the gowns passed technical now?"*

82. Mr James told Mr Page: "*We're still awaiting the BS EN 556-1, I think.*"

83. Mr Page answered later on 9 June 2020 by providing a screen shot from a slightly different version of the ETRD (not the one he had been sent) saying: "*Please see the attached. We should be 100% now approved with the certificate that we sent*

your earlier, please also see attached. It basically either EN 13795 or 556-1. We have EN 13795 so our sterile gowns are good to go! I hope tomorrow will be better news getting this over the line."

84. The screenshot was of a table with technical requirements for non-sterile and sterile surgical gowns. There was a hand drawn circle around the requirement for the latter, which suggested that a supplier of sterile surgical gowns had to comply either with BS EN 13795-1:2019 or AAMI PB70 (US standard) (all levels accepted or equivalent) and EN 556-1. The screenshot also stated that the gowns must *"have a clear CE Mark"*.

85. Shortly after, Mr James responded that "*We seem to be looking at subtly different variations of the spec. This is what is on the govuk website*". He attached a screenshot from the gov.uk website (attaching a screenshot of the PDF "Essential Technical Specifications_5.pdf".). He went on to say: "*The Technical Team have specifically asked for this. If you can point me at where the documentation provided confirms the SAL then I will be able to explain this to them and hopefully get it over the line.*"

86. Mr Page provided no such certification documentation. It is common ground that EN 556 certification was never provided. Mr Page responded that: "*We are certain that we are 100% compliant. I will email you more information tomorrow.*"

87. On 10 June 2020, Mr Page wrote:

> "Please see the attached certificate. These guys sterilise for our factory which shows iso11137.
>
> This is the indication of SAL 10.
>
> Hopefully this is all your technical department requires."

88. The document he sent through was a certificate from a German certification body, TÜV SÜD Product Service GmbH, for Wuxi Futeng Irradiation Technology Co. Ltd. That was a certification in respect of (i) page 1: EN ISO 13485 (see above – not relevant); (ii) EN ISO 11137-1:2015 "*Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)*." In other words, as explained above, it demonstrated certification of a process for sterilisation. It said nothing about Part 2 of ISO 11137, nor about achieving SAL 10^{-6}.

89. Mr James replied: *"Thanks Anthony, I've actioned it right away and will monitor throughout the day"*

90. Mr Page continued to chase asking for news, and how long it would be. Later that day Rachel Camiss, a member of the PPE Cell, working in Supply Chain PPE Sourcing and COVID-19 Emergency Supply Chain Response PPE Sourcing sent an email titled *"Urgent VIP TA Review FAO Gary/Billy SUB MXID 15012 PPE Medpro Limited Gowns"* with high importance to Mr Clarke escalating the

project and requesting support in looking into this the same day because "*the supplier has a [tendency] to escalate to the private offices*".

91. Also on 12 June Mr James was chasing on an apparently separate submission numbered 19368 saying the supplier said he could not hold stock much longer. The reply from Mr Smith was "*Tech assurance have placed this on hold as we require images of the product and packaging on offer. These images need to show all sides of the product carton and any instructions for use so that we can determine if the labelling meets the Gov.uk NHS requirements. This includes the required CE mark and manufacturers name and address. Please note that the rest of the submission has already been reviewed and is acceptable.*"

92. This was passed on to Mr Page: "*Latest news from the Tech team: The submission is still on hold as we believe that the NHS requirements on labelling are not met and as such would require derogation from the UK regulatory authority MHRA. We are preparing a derogation request to try and have this requirement waived*". There was however no evidence of such a derogation request ever having been submitted for the gowns which are the subject of this claim.

93. Meanwhile Mr Clarke was considering the documents submitted. He checked the authenticity of the Certificate of Free Sale with the MHRA satisfying himself that WTT was legitimate. Having looked at the images submitted, including the CE mark (without notified body number) he formed the view that Medpro understood the requirements of sterility and thought, with the ISO 11137 certification and the picture of the CE mark there was sufficient evidence that the manufacturer could comply with ETRD requirements. It was for him to satisfy himself that there was a valid CE mark. He accepted in cross examination that he was mistaken to form the view that this was a valid CE mark for this product. He did not submit a derogation request.

94. Then about 2 hours later, Mr Clarke sent an email to inter alia Mr James. The subject line read "*RE: Urgent VIP TA Review FAO Billy/Gary SUB MXID 15012 PPE Medpro Limited Gowns – ACCEPT*". Mr Clarke wrote: "*... Medpro Gowns submission has now been approved in Mendix*."

95. The Mendix entry states:

> "MoD Tech Assurance Review – 12/06/2020 - ACCEPT
>
> Confirmation received from MHRA that products may have CE mark affixed. "Certificate of Free Sale for Exportation" (MHRA ref: Certificate number: […]"

96. The good news was passed on to Mr Page by Mr James in an email with the subject line: "*Gowns have been approved by Technical!*" This message is at the heart of Medpro's case.

Closing

97. The offer, having passed Technical, was advanced to Closing.

98. On 13 June 2020, Nick Graham of Closing emailed Mr Page. He wrote, subject to contract, setting out various proposed details, including in relation to delivery and he attached the "*latest version of the DHSC order form*". He added that "*Red highlighted sections are for DHSC to complete, yellow sections are to be agreed, and blue sections are for you to verify/complete as necessary*." Section 3 of Schedule 1 regarding quality assurance standards was marked yellow, with the relevant standards to be inserted, and for the box with yellow highlight to be ticked if applicable (which it was). The attachments also included Schedule 2.

99. After speaking with Mr Graham on 14 June 2020, Mr Page set out his record of their conversation in an email to Mr Graham. He sent two Dropbox links for the two proposed factories in Medpro's gowns offer: WTT and Kunshan which Mr Page said were both on the whitelist and for which information had been sent to Mr James previously. Mr Page requested that Mr James confirm that all was in order as "*Nick is keen to conclude matters today*". He also emailed Mr Graham providing him with the same details for the two factories, requesting that he too check and confirm that all is in order. He added: "*For the avoidance of doubt if we only have one factory that has been signed off we can allocate more production capacity to the NHS and still can make our delivery schedule"*.

100. Mr Graham responded later that evening explaining that he was "*progressing with the order form and product registration*" but that he had not been able to find evidence that the "technical approvers" had seen the certifications for Kunshan. He asked Mr Page to forward the technical documents so that he could *"try to push these through*". In the meantime, he explained, he was "*populating the order form with that information where possible*" and, pending a response from Technical, hoped to send the completed order form by midday on 15 June 2020.

101. Shortly thereafter Mr Page sent through product packs for both factories. Mr Graham confirmed receipt and added that was trying to find out if Technical had also approved Kunshan. Shortly thereafter, Mr Graham emailed Mr James noting that the Mendix entry only covered WTT, and the QMS [quality management systems] for the sterilisation company/process. He stated he would confirm with Mr Clarke if he had done technical assurance on the second manufacturer. Mr James stated that Medpro had only ever sent over the first factory, and that they *"have form for wanting to submit multiple factories after the event but they also recognise that the second factory will need to go through QA as well"*.

102. Mr Page also emailed Mr Graham, stating he would send through a screenshot showing the Kunshan Jiehong factory to be on the whitelist. He submitted two screenshots, one in Chinese, and one bilingual which show the factory on a list, though the title of the list is not apparent.

103. On 15 June 2020, Mr Graham submitted the proposed deal to purchase 50 million sterile surgical gowns for £275,550,000 (ex VAT) (£5.50 per unit) for approval by the Deals Committee. The products and quantity were described as "*50 million Sterile surgical gowns compliant to EN 13795-1:2019*". The form further states:

> "Both manufacturers are on the 'White List', however only the first (Wujiang Tutaike) has passed technical verification. This

> will be carried out with the MOD QA team prior to any order being placed.
>
> The supplier will carry out ongoing factory inspection – representatives of [Medpro] will conduct inspections of the factory to review material compliance and process verification. This audit process is not contracted to a 3rd party, but carried out by their personnel. Inspection/ Verification & QA – before any goods leave the factory the [Medpro] compliance team is on hand to conduct a through [sic] inspection of the product, inner and outer packaging and ensure that the proper certification accompanies the goods through to export. Whilst many exporters and international clients rely on third party inspections such as SGS, [Medpro] conducts this aspect internally. It is not proposed to undertake further DD given the process and procedures put in place by [Medpro]."

104. Mr Graham informed Mr Page of the submission and asked: "*I've still not seen anything on approval of the second factory; if that turns out to be an issue is there any chance of doing the full deal with Wujian [sic] or is there insufficient capacity?*". Mr Page's response was that "*We can do the full capacity at Wujian [sic]*", (i.e. at WTT). His email said that Medpro had "*a 100% record on quality and delivery, we are superb at managing every situation as it comes up*."

105. Later on 15 June, Mr Graham for the first time sent the draft order form which he had populated as much as possible. He asked Mr Page to complete and check that he was content with the draft, especially sections highlighted in blue. Mr Graham reiterated that sections highlighted in yellow were still to be agreed and noted that he did not yet need a signature from Mr Page as the annex with full specification needed to be added. By that stage, section 3 of Schedule 1 on quality assurance standards contained the single code EN 13795-1:2019. Mr Page replied to this, stating that "Everything looks 100% correct", and reattaching the order form which he had signed.

106. On 15 June 2020, there were then several internal PPE Cell emails relating to the Medpro offer. These included Diane Neilsen asking when TLT review is expected. The Closing committee met late that night. The minutes are redacted but apparently shows that no decision was reached. Concerns were expressed as to whether there was a need for such a large order of sterile surgical gowns and also as to a large order to a new company. There were also issues about Medpro being a small company and using a factory that had not been checked – Kunshan. In the event, the message was passed back to Medpro to see if it would reduce the volume to be supplied from 50 million gowns to 25 million gowns "*not sure that our demand signals is as high as previously thought which does give us an opportunity to present an alternative deal — if you could provide a total of 25m gowns with deliveries going out to the end of July, it both reduces the DHSC financial exposure and gives us more flexibility in warehousing and distribution"*.

107. Mr Page was understandably disappointed by this news, and replied in terms that stressed Medpro's competence and reliability: "*We have all been in business together for over 20 years, we have 100 people on the ground in China and supply*

retailers and Governments all over the world. PPE Medpro was specifically set up to supply the NHS in the UK only. … We want to reassure the NHS that we always deliver 100% quality and on time." He goes on to ask what more was needed "*to get this over the line*".

108. On 17 June 2020, Mr Graham and Mr Page spoke by phone. Mr Page said that Medpro was content to proceed with the reduced number of 25m gowns at a unit price of £5.50 saying if he felt the order "*will go through at 25 million units I will convince the team. Our margin will be tiny at 25 million but I can sell it to them hoping that a 2nd order will come after this one*".

109. Mr Graham relayed this to Mr James, cc-ing Mr Townsend and a Rachel German. A little later, Mr Beard emailed Mr Graham with news that: "*This was approved tonight*." In fact, the minutes of that meeting state something rather different, namely, that it was approved, but "subject to demand".

110. Later Mr Graham emailed to tell Mr Page that "*The deal was approved at the committee tonight, so I'm just revising the order form and will get the updated draft over to you asap. I know you're aware of our process, but for the sake of completeness I always remind suppliers at this point that deal approval doesn't necessarily mean DHSC will approve the contract. I can't see any reason why it would be rejected having got to this point, but I can't make any guarantees*". That reflects the fact that on the documents it was a conditional approval, "subject to demand".

111. Mr Graham attached an Order form and other contractual documents requesting that if Mr Page was willing to be bound by these, he should return a signed copy of the order form, which would be submitted to DHSC for consideration and potential approval. The factory table on page 4 of the Order Form records the product description as "TKK-C01 Sterile Surgical Gown" and the only factory listed is "Wujiang Tutaike Textiles & Finishing Co., Ltd". Medpro relies fairly heavily on the contents of this document, in particular:

    a. The applicable standard listed for quality assurance in section 3 of Schedule 1 remained EN 13795;

    b. Section 6 of the Order Form left the box titled "CE#" blank;

    c. Section 7 provided that "specification of the Deliverables" was as set out in the Annex. The Annex included the documents supplied by Medpro as part of its offer to the DHSC. The photos attached to the Order Form displaying an invalid CE mark (i.e., one without a notified body number). The boxes in Section 7 were checked to "*confirm which documents are inserted into the Annex*". In line with the photos the CE Certification box was not checked, while Product Test spec, Test Certification and EN Certification were. This appeared to reflect a confusion on Mr Graham's part as to whether it was feasible to check more than one box;

    d. Schedule 1 referred only to EN 13795 as the relevant quality assurance standard.

112. Mr Graham later noticed a minor error in a table in section 6 of the order form, whereby he omitted to sum up the total values for each size. He re-submitted an updated version of the form.

113. Early on 18 June 2020 Mr Page sent Mr Graham back the contract signed by him on behalf of Medpro.

114. On the same day, Mr Graham emailed the Finance Team requesting a Purchase Order to be raised with Medpro for the purchase of 25m WTT sterile surgical gowns at a total cost of £137.5m. He included as part of the submission pack a "*Request for approval of spend against HMT Delegated Funding*". Against the box entitled "*What certifications are applicable to this order? (E.g. CAPA, CE/EN certificates?*)" it was written:

> "Technical specifications incorporated in to draft contract and technical clearances attached in submission - they are also on Mendix"

115. Against the box entitled "*What evidence is there that stock meets this certification?*" it was written: "*MOD QA confirmation attached - also on Mendix*". It was also stated that "*The Governance Board has approved this submission.*" Then, against the box entitled "*Description of goods (including sizing and technical certification)*" it was written: "*This order would secure 25 million sterile surgical gowns, compliant to EN 13795-1:2019 in a range of sizes from XS to XXL, delivered ex-works to Uniserve representatives in China.*"

116. Mr Graham also included a document called "*PPE Closing Team Contract Management Plan (CMP) & Handover Key Notes*". It had a box called "Contract Delivery Terms" on the first page. That had three options and only the box "Delivered 'Ex Works'" was checked.

117. The screenshot of Mendix showed, in the "Approval" section, that the decision was "Progress", and the comment box populated as follows:

> "MoD Tech Assurance Review – 12/06/2020 - ACCEPT
>
> Confirmation received from MHRA that products may have CE mark affixed. "Certificate of Free Sale for Exportation" (MHRA ref:…"

118. It seems that at about this time, the Medpro "Submission to DHSC Checklist v4" was completed within the PPE Cell. There were several headings, one of which was "Technical Approval". Under that heading, "Technical Approval" was confirmed, and it was indicated that the "Technical Documents" were in the order form and: "*Technical specification or similar for all items in scope; Timestamped pictures of the equipment (where available), Appropriate medical certification*"

119. On 19 June 2020, Mr Graham emailed Mr Page explaining that:

> "I've just heard that there is a meeting at 1pm to discuss the demand for gowns, and I've heard a hint that they may be looking to cancel some orders if we have enough quantities

> coming in. With this in mind, I feel obliged to warn against making any commitments until you get a fully signed contract, as it would be at your own risk. I'm not trying to gently break any news here; I simply don't know what will happen this afternoon but there are differing views on the incoming stock vs. potential future orders vs. actual and forecast usage stats?"

120. In response, despite Mr Graham's warning that the contract had not yet been approved, Mr Page said that "*As soon as we had committee sign off on Wednesday we bought the production capacity for 25 million units. There is now a huge cash outlay from our side and we are not taking any deposits up front to help the NHS. The majority of companies are taking deposits upfront. The delivery dates are extremely tight as you know so that's why we had to go ahead*".

121. Mr Page chased repeatedly emphasising that Medpro had now gone beyond the point of no return and that to secure the contract the price was up for discussion. In the evening of 19 June he pressed his case thus:

> "As you know, we understood the contract sign off to be a formality and due to the tight timetable, we have already committed a huge amount of capital to materials, packaging and production capacity to ensure we meet the deadlines. We have already agreed to a deal on the basis of no deposits and a competitive pricing arrangement, which left us with a considerable cashflow commitment and a tight margin. In order to secure the contract and protect our outlay we can move to an absolute best price per gown of £5.18. To be clear, this removes our margin entirely and is now priced to ensure we deliver what we have committed to. Our production schedule is attached. … Our schedule and pricing is [sic] based on both approved factories and twice weekly collections as a minimum".

122. Mr Graham responded stating: *"I have a concern that your proposal includes both factories – while both are cleared to export from China, only one has currently passed technical approval, so I don't know how this could affect things."* Mr Page replied: *"They are both definitely approved and cleared for use. They were both noted on the original contract when we were discussing an order of 50m units"*. Mr Graham replied that he had not initially received any documents relating to the second factory, and promised to double-check: *"if you remember I didn't initially have any documents relating to the second factory, and therefore when we reduced the order volumes it was for a single factory"*. Mr Page then reverted: *"Both factories are definitely approved at all levels as they were both noted and included on the first proposed contract when it was potentially an order for 50m gowns".*

123. Mr Page later sent all the documentation which he said showed that the second factory is "fully compliant", stating "*I believe all of this has previously been provided as this factory was on the draft contract when the gown order was 50m. Also included is the business licence. There should be no obstacles for this factory now. Can you please check this is all in order and we can have factory 2 on our*

25m gown proposal? Clearly time is of the essence". Attached were several Chinese documents and screenshots of online portals.

124. At this point Mr Page engaged his "big gun" – contacting Baroness Mone who then took up the fight on behalf of Medpro direct with Chris Hall from the Cabinet Office threatening further escalation. Baroness Mone was plainly of the view that there was a contract; "*the committee sign off, the finance sign off, the verbal conversations on the urgency of goods and the signed returned contract, all constitutes a contract, with a legal and moral obligation on DHSC".* DHSC responded that the whole matter still remained subject to contract and that Medpro's decision to commence production was theirs alone.

125. Between 19 June 2020 and 24 June 2020, there was then considerable to-ing and fro-ing within the PPE Cell as to whether to proceed with the Medpro offer and if so whether one factory or both. Inter alia there was some discussion about whether sterile gowns were a COVID requirement at all. Nonetheless, the Medpro offer was still proceeding.

126. Mr Graham was also chasing on whether Technical would approve the proposed second factory, Kunshan. Mr Page had sent through various materials through to Mr Graham in respect of Kunshan. He then wrote to Baroness Mone claiming that "*As you know we were told that this factory was approved, it was on our order for 50 million units so we are a bit confused […] Tomorrow we will submit our best price. As I said our margin will be tiny or possible nothing at all as we have bought all the production capacity upfront. We really need to achieve a positive outcome to this extremely disappointing situation*".

127. In the morning of 22 June 2020, Mr Page emailed Mr Graham with a new proposal in the following terms:

> "The great news is that we can deliver 6 million gowns by 30th June with the balance of 19 million gowns provided by the end of July. We can do daily or weekly pick-ups. Our revised production schedule is attached. Our price is £4.88 and this is now priced to minimise our exposure and the costs we've already funded. Our quoted price now is simply an attempt to recover the millions of pounds we have paid upfront to deliver on time. Key to this is that our 2nd joint venture factory is approved. …"

128. Mr Graham requested urgent quality assurance assistance from David Moore (Mendix Technical lead), copying amongst others Mr Beard and Mr Townsend, for the second factory to be approved. He stated: *"From their [Medpro's] perspective they submitted this 3 weeks ago, however I haven't seen anything to suggest it's completed technical approval"* and went on to say: "*There is some urgency in these queries as a decision is to be made today which, if any, deal is to be pursued, and there are political considerations to at least one".*

Final Approval and Contract

129. On 22 June, Mr Townsend sought approval for the Medpro Gowns deal (25m gowns until August) from Emily Lawson, Chief Commercial Officer, and Jonathan Marron, Director General for the Office for Health Improvement and Disparities. Mr Townsend followed up again in the evening, since *"both vendors are very keen to understand when a decision is likely".* In a separate chain, Jen Shaw, Private Secretary to Jonathan Marron, queried about the need for sterile as opposed to non-sterile gowns. Mr Townsend replied that the recommendation was not for more non-sterile gowns. This was followed by an email from Emily Lawson: *"There is an ongoing need for sterile gowns and the price is now excellent. I would recommend to the AO [Accounting Officer] he approve these deals*". Further up the line, the next day it was noted: "*it rests with Emily and Jonathan to make a recommendation to David Williams. If there is further information that Emily and Jonathan need to make their assessment, can you please let us know?*"

130. On 23 June, Mr Page chased Mr Graham again: *"Please can we have an urgent update on the gown order. We have now lost a further 24 hours and that is on the back of lost time last week. We were told the priority was delivering as much stock in June yet every day we lost further production time and capacity as nobody seems capable of making a simple decision. It is now 24 hours since we submitted our best and final offer and you confirmed the other competing firm submitted their final offer on Sunday evening. How has a decision not been reached and approved?"*

131. Mr Graham responded, stating: *"We are all continuing to chase on this, and there are Directors personally involved in trying to elicit a decision. We have been assured that as soon as the answer is known it will be flowed down, and for my part I will certainly be in touch straight away after I receive the decision"*.

132. Mr Page responded the following way: *"In my 20 years of working I've never known a situation like this. How can it possibly still be that a decision has not been reached? One company is told they have been successful and one is told they are unsuccessful. It is verging on the farcical that one of the key requirements was how much stock could be provided by 30th June yet the powers that be are happy to waste further time making a simple decision. If the private sector operated in the same way as Government the entire economy would come to a grinding halt! Please can you ask those making the decision to have the courtesy and professionalism to pass their decision on."*

133. Mr Graham replied: *"I can completely understand your frustration, and this isn't something I've experienced in my time on COVID so far. All I can say is that we are pushing as hard as possible, and we'll keep you updated as soon as anything changes."*

134. At the same time Mr Graham chased up on outstanding matters.

> "If we do get approval, we will need to update the contract to reflect the revised pricing, the second factory (which has now been cleared, subject to the caveats below), and the need to

> reflect the delays to the production schedule. With that in mind, I've attached an updated draft contract, … The only other thing to notice in the order form is that we've got an additional clause 12.8 which relates to the declaration of conformity – ...
>
> In terms of the second factory/product clearance, the only queries raised were that a) the approvers couldn't see evidence of the packaging (I assume the boxes, rather than folding/bagging etc.) to confirm that it met the CE requirements – if you have photos of boxes from this factory I think that's all they need for this, and b) in the declaration of conformity (DoC) Minor there is a minor error identified in that it Refers to Council Directive 92/42/EEC, whereas it should read 93/42/EEC."

135. On 25 June, Mr Page submitted a revised schedule in response to Mr Graham's request, and also attached photographic evidence of the final Medpro box for collection and delivery. The description of the gowns from Kunshan contained a valid CE label with notified body number which was provided by a notified body in Germany. This submission was approved by Mr Larter of Technical: *"Technical assurance confirms that based on this and previous evidence provided the submission is acceptable to proceed to closing"*. Thus, the second factory, Kunshan Jiehong, did submit proof of valid CE marking. It was approved by Technical on 25 June 2020 for the proposed supply of the gowns.

136. Meanwhile COVID-19 Finance Operations submitted the Medpro submission (as well as a second offer) to the Accounting Officer for approval on 24 June. A member of the Finance Operations team then requested sight of the original submission for Medpro "*in anticipation of [the Accounting Officer] approving",* as this would be needed to set up the Purchase Order. This was sent through by Mr Graham.

137. Then on 25 June 2020 Mr Page sent through the signed Order Form which now included Kunshan. The price was now at £4.88 a gown, giving a total of £122 million.

138. On 26 June 2020, with Mr Williams' authority which must somehow have been communicated to him, Mr Ed James signed the Contract for DHSC. In the morning of 27 June 2020, Mr Graham forwarded to Mr Page the Contract signed by DHSC. The Purchase Order followed on 29 June 2020.

139. The relevant terms of the contractual documents are given in Appendix 2. For present purposes the central point to note concerns the slightly complex way in which the Contract was constructed. It comprised:

    a. An order form (signed on behalf of both parties); the Order Form is stated (Schedule 1, clause 2.2) to "include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Suppliers responses, proposals and/or method statements to meet those requirements, and any clarifications of the Supplier's responses,

proposals and/or method statements as included [i]n these terms and conditions";

b. Schedule 1 ("Key Provisions"), which contained two mandatory provisions (clauses 1 and 2) and various provisions which were to apply only where they "have been checked" (i.e. check-marked). Clauses 3, 4, 5, 8, 9 and 12 were checked;

c. Schedules 2, 3, and 4 which consist of various general conditions, definitions, and "additional special conditions";

d. A set of annexures marked "A1" to "A9" which were said to be a "technical specification". These were the various documents relating to the factories' certification and packaging;

e. The Annexes to the Contract were split as between the two factories in which the Gowns were to be manufactured: Annexes 1-4 relate to WTT, and Annexes 5-9 relate to Kunshan Jiehong:

i) Annex A.1 – Packaging specifications – Wujiang Tutaike

ii) Annex A.2 – Test Certification – Wujiang Tutaike

iii) Annex A.3 – Certificate of Conformity – Wujiang Tutaike

iv) Annex A.4 – QMS Certification – Wujiang Tutaike

v) Annex A.5 – Packaging specifications (individual) – Kunshan Jiehong

vi) Annex A.6 – Packaging specifications (carton) – Kunshan Jiehong

vii) Annex A.7 - Test Certification – Kunshan Jiehong

viii) Annex A.8 – Declaration of Conformity (updated) -Kunshan Jiehong

ix) Annex A.9 – Technical Specifications and QMS Certifications- Kunshan Jiehong

140. Between 8 July 2020 and 28 August 2020, DHSC paid £121,999,219.20 to Medpro in consideration under the Contract for the Gowns.

Manufacturing, delivery and inspection

141. Ironically, ultimately the gowns were manufactured by the WTT factory. The Kunshan Jiehong factory (which had submitted full proof of valid CE marking) was not used.

142. The gowns were sterilised by a terminal (i.e. post-manufacture) process of electron beam irradiation. This is a process in which high energy electrons are used to bombard the product to be sterilised, by scanning in a sweeping motion.

It was carried out by seven other factories: CGN Dasheng, Shanghai Eagle High Technology Co. Ltd, Wuxi Futeng, Zhejiang Hanqing Biotechnology Co. Ltd, Nanjing Xi Yue Technology Co. Ltd, Shanghai Shuneng Irradiation Technology Co. Ltd and Sterigenics Shanghai E-Beam Co. Ltd. Of those seven sterilisation facilities, Wuxi Futeng had been notified to the PPE Cell's Technical team in the course of the procurement exercise.

143. DHSC arranged for the collection of the Gowns from the sterilisation plants in China between approximately 12 July 2020 and 3 September 2020, on an Incoterms "ex works" basis. The Gowns were supplied in cardboard boxes of 90 gowns. Each box gave the WTT origin and a lot number as well as a generic CE mark (with no notified body number). The boxes also stated *"Sterile Surgical Gown. Sterilized. Sterile R"* and gave the contract number and Medpro's details. Within the boxes each Gown was in a sealed plastic bag. Inside the bag was a label stating "Sterile Surgical Gown" as well as Medpro's logo, sizing details and details of the EN 13795 requirements. AT the bottom of each label was the notation *"CE .... Sterilized. Sterile R"*. Both from the boxes and from the presentation of the individual gowns it was therefore clear that the Gowns claimed to be sterile; and that they did not have the conventional CE marking including a notified body number.

144. The gowns were loaded by Medpro's agents into shipping containers, and the containers were then sealed and taken to port for shipment to the UK. Medpro made the arrangements with Uniserve, which provided logistics services to DHSC during the Covid-19 pandemic. The Uniserve contract contained a number of express obligations on Uniserve which indicate that Uniserve was to carry out inspections and perform quality control and other checks on the gowns collected from the sterilisation plant. That was to be done either at the gates of the sterilisation plants or at the freight stations in port. There was however a degree of doubt about whether Uniserve ever did conduct inspections on behalf of DHSC.

145. There were then 21 voyages with shipments of gowns departing China between 21 July 2020 and 13 September and arriving in the UK between 20 August and 23 October 2020.

146. UK-side storage and logistics were managed on DHSC's behalf by specialist companies. The gowns were moved to storage sites in shipping containers and were then unloaded and palletised for storage in warehouses, or kept in shipping containers at warehouse or container park sites.

147. Supply Chain Coordination Limited ("SCCL") managed the NHS's supply chain and the storage of goods bought during the pandemic. It compiled a "Freight Records Spreadsheet", which shows the various voyages of gowns by reference to individual containers and their storage location as at July 2023. A simplified version, which has been grouped by voyage in chronological order, shows that, upon arrival in the UK, gowns were either unloaded into warehouses or into shipping containers (and sometimes unloaded into warehouses on a later date). To minimise costs, shipping line containers were generally destuffed and the goods loaded into other containers. This might have happened near the port of arrival or at the warehouse site.

148. SCCL has also produced a "Storage Costs Spreadsheet". The data was obtained from frontline organisations involved in managing the stock and put together by SCCL's data analysis team. It shows (at a high level) where the gowns were between 15 February 2021 and May 2024. DHSC argues that this demonstrates that they were stored in warehouses or containers during that time and is also relied on in support of DHSC's storage costs claim. It is considered further below in this context.

149. On 11 September 2020, a Ms Zarah Naeem conducted a MHRA Checklist clearing Daventry Stock in respect of the WTT Gowns. The evidence, including Ms Breslin's cross-examination of Ms Naeem, indicated that there was no inspection before this date. The Checklist was detailed and was very specific as to the requirements of the regulations, including notified body number for sterile gowns. She completed the checklist via a review of photos of some of the stock and any documents submitted with them. As to the latter, there was apparently an Internet report, because Ms Naeem emailed Charlotte Murphy stating: *"Please can you confirm/verify this Intertet report is genuine. It is related to a large gown order for the NHS".* In completing the checklist on the gowns, she recorded that there was a "*CE mark but no CE NB number*".

150. On 19 October 2020, Intertek sent an email to NHS Tech Assurance (following the distinct query as to the report's provenance) stating, in relation to the testing report in relation to Medpro's Gowns: *"The report is not issued by us."*

151. These two anomalies having been noticed, Ms Naeem sent the submission on to Clipper (a UK-side logistics company providing services to DHSC and specifically providing the material for assessments) for review.

152. On 22 October 2020, Clipper contacted Mr Page asking *inter alia* for declarations of conformity to the MDR, an Annex V a certificate for sterility and an explanation of why there was "*no NB number next to CE mark… (indicating sterility)*" as well as a QMS certificate.

153. Separately, around 28 October 2020, the PPE Cell found during a technical assessment of a further proposal to supply gowns by Medpro that it had provided an inauthentic report from a testing company called Intertek. That day, Dr Darren Mann wrote to the MHRA stating:

> "Following our technical assessment of a proposal for a surgical gown to be supplied by PPE Medpro (manufactured by Wuijang [sic] Tutaike Textile & Finishing co. Ltd) we have found that the test report provided is inauthentic. Please see email indicating that the test certificate provided was not issued by Intertek.
>
> Please note that you are currently reviewing surgical gown products already supplied by the supplier: SKU GCIS0113 and GCIS0114 Medpro currently locked at Daventry (please see earlier correspondence referring).

> Internal Tech Assurance protocols provide for inauthentic documents and certificates to be referred to Anti- Fraud Office and the relevant Regulator for awareness and action.
>
> We wish to ensure that other healthcare product procurers are made aware of the presence of these inauthentic documents and for caution to be emphasised.
>
> Grateful if MHRA could manage this information according to your procedures and to engage with Medpro accordingly."

154. Nicole Small of the MHRA then emailed Devices Compliance at the MHRA, with Ms Naeem in CC, stating the following, after which a referral incident was created at the MHRA:

> "Issue:
>
> (1) Fake report – PPE/MD certificate to a product standard BS EN 13795 (SHAT doc Intertek)
>
> (2) Non-conformity – CE mark on label but no Notified Body number against it for a sterile product. No assurance/evidence that sterility aspects (Annex V or equivalent) has been achieved in order to place CE mark on this 'sterile' device. DSSG will pursue this subject to resolution of the fake report from Intertek
>
> Stock locked in Daventry currently …
>
> MHRA will not approve this to stock [sic] to be released unless point 1 has been resolved"

155. On 29 October, Ms Small updated Devices Compliance, again copying in Ms Naeem, stating:

> "Update:
>
> The Intertek fake report (to BS EN 13795 SHAT 06648491) was sent to DHSC team by Medpro to provide evidence for potential future procurement.
>
> As mentioned in our call, MHRA also hold a different test report to BS EN 13795 SHAT 06497575 which was provided within a procurement system called OneWorld relating to Daventry stock already supplied by Medpro. Verification of this report has not been established yet.
>
> So we hold two reports – one fake – one TBD for the same gowns from the supplier Medpro.
>
> The label says sterile product but CE mark does not hold Notified Body number against it to demonstrate conformity assessment to Annex V or alternative has been carried out by NB. DSSG has asked for this certificate.

> Please can you investigate liaising with DSSG as appropriate.
>
> The stock in UK will not be released into the supply chain until resolved."

156. This prompted the MHRA to raise both matters as issues in relation to Medpro and to refuse to release the stock unless the issues were resolved.

157. On 4 November, Alan Taylor, Senior Devices Inspector at MHRA, sent a letter to Medpro, enquiring as to why the Gowns had been supplied in packaging bearing a CE mark with no notified body number, and requesting a certified copy of the EC certification issued by an appropriate notified body that related to the gowns to give assurance that they were sterile as claimed.

158. On 6 November, Mr Page emailed Mr Taylor setting out Medpro's position on the Gowns' compliance with the Contract. He referred to the Contract and, with reference to section 6 of the Order Form, explained that "[t]*he deliverables table clearly omits the "CE #." This is because TTK's sterile surgical gown did not have the requisite Notify Body accreditations, and we made no representations that it did. [Compare the Mask Contract which includes requirement for CE mark]*". He also referred to section 7 of the Order form which "*clearly omits the CE certification as a specification*". Mr Page went on to add that: "*The Gown Contract omits any requirement for CE marking and affixing of NB numbers for the reasons stated above. This is of particular relevance to the TTK manufactured gowns (the JHSTG* [i.e. the Kunshan Jiehong factory] *manufactured gowns are CE marked with NB number and the technical and packing documentation supports this)*". [There were, in fact, no gowns manufactured by the Kunshan Jiehong factory.]

159. On 17 November, Mr Taylor responded to Mr Page's initial position. Mr Taylor explained that the Gowns had been CE marked and labelled as "Sterile R", despite there being no notified body certification or relevant conformity assessment. Mr Taylor states that he understands that Mr Page himself also does not believe that the stock has a notified body certification. He goes on to state that "*The CE mark should only be affixed once all relevant requirements of the Medical Device Directive 93/42/EEC have been applied. This includes completing the relevant conformity assessment (e.g. Annex V) for sterility aspects of Class I medical device. If the requirements of the Regulations have not been met in full, the CE mark of the gowns should not be affixed to the label*". Mr Taylor stated that "*On this basis I will advise that the stock at Daventry cannot be released to the NHS until this matter is resolved satisfactorily and the product has the correct notified body certification".* Mr Page responded to the email of Mr Taylor, indicating that he was keen to resolve the issue and proposing a call, which took place the following day. He chased Mr Taylor again on 18 November. Mr Taylor then asked for questions to be shared in advance, noting he was not going to be able to engage in the contractual matters raised by Mr Page.

160. After Mr Page chased Mr Taylor for an update on the process on 23 November, Mr Taylor responded on that day stating: *"I think we agreed that you would talk with the manufacturer or EU representative and ask them to provide suggested corrective action regarding the labelling of any further relevant products"*.

161. Also on 23 November, Mr Page emailed Mr Taylor in relation to the Intertek report which was flagged as not being genuine, stating:

> "It has come to our attention that a marked up copy of an Intertek report SHAT06648491 dated 28th September 2020 was incorrectly submitted to the DHSC in connection with a procurement exercise for Impervious Gown…
>
> Although the procurement exercise did not proceed and no BMPC8 gowns have been supplied, whether in the UK or elsewhere, in accordance with best practice we wish to bring this error to your attention immediately, and recall the copy of SHAT06648491 report dated 28th September 2020. We have the original certified Intertek report and attach a copy for your records."

162. On 24 November, Mr Page responded to an email from Mr Taylor in which he had raised various questions. As regards the labelling of the gowns, Mr Page stated:

> "As you have made clear, goods do not meet the regulations required to affix the CE mark, we have already given you an explanation as to why these goods were offered, ordered and delivered. Is there a regulatory path to resolve this? Or are there other paths to deal with this, such as a relabelling exercise or derogation." Mr Page also went on to say: "We confirm that the goods do not have a NB number. Having already talked through the history of the product and how we came to supply this to the DHSC, if an NB number cannot be applied, can the goods be relabelled and re-purposed as non-sterile gowns [subject to approval and instruction from our client the DHSC]. Or does the MHRA have any other solutions that we can consider and action?" As regards derogation, Mr Page stated "Derogation was mentioned to us in correspondence with the DHSC procurement & technical assurance team prior to contract award. It was then our understanding that they would have worked to obtain this status. If this has not been done by the relevant teams, can we work with you and your team to have this done on our clients [sic] behalf?"

163. Responding on 30 November, Mr Taylor stated that: *"The only method to bring this product into compliance is for it to have supporting notified body certification"*. He also went on to say: *"I appreciate all the information and suggestions you have provided me with but the gowns at Daventry will not be considered compliant by the MHRA until they have notified body certification"*.

164. Between 30 November 2020 and 22 December 2020, there was further contact between Mr Page and the MHRA, and between Mr Page and DHSC, but no progress was made.

Rejection of the Gowns

165. On 23 December 2020, DHSC rejected the Gowns by the Rejection Notice:

> "Faults with the Goods
>
> 3. Under the Contract Medpro is required to supply Goods to DHSC for use in the NHS in accordance with:
>
> a. BS EN 13795:2019 (clause 3 of Schedule 1 of the Contract); and
>
> b. The relevant requirements of applicable laws and regulations applicable to the supply of PPE, including, as applicable, the EU PPE Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 and the Medical Device Regulations 2002 ("the PPE Laws") (Clause 12.2 of Schedule I of the Contract).
>
> 4. Further, the Contract requires Medpro to ensure:
>
> a. The appropriate conformity assessment procedures(s) applicable to the PPE Goods have been followed:
>
> b. All declarations of conformity and approvals required by PPE Laws are in place prior to delivery of any PPE Goods to the Authority;
>
> c. Where required by PPE Laws, there is a CE Mark affixed to the PPE Goods in accordance with the PPE Laws; and
>
> d. Where necessary current EC-type examination certificates are in place for the PPE Goods.
>
> Further, Medpro is required to use reasonable skill and care in the manufacture of the PPE Goods (Schedule 2 clause 7.1.3) and supply PPE Goods which are of satisfactory quality and fit for their intended purpose (as warranted at Schedule 2 paragraph 7.1.1).
>
> 6. In breach of the Contract, Medpro has delivered Goods which, amongst other things, are not compliant with the PPE Laws and/ or Medpro has not ensured compliance with the requirements set out in the Contract and summarised at 4(a) to (d) below, and/ or the Goods are not fit for their intended purpose, namely use as sterile surgical gowns in the NHS.
>
> 7. As you are aware, the Goods have not been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) for use as sterile surgical gowns in the UK. We understand that MHRA have written to Medpro direct setting out the reasons why the Goods are non-compliant with the PPE Laws so far as they relate to medical devices. I refer you to

> MHRA's correspondence for full details in this respect, but in summary, Medpro has failed to provide the essential certification MHRA requires to establish that the Goods have been reliably sterilised for medical use. In the absence of a satisfactory response from you the Goods have been found by MHRA to be non-compliant with the PPE Laws (relating to medical devices), with improperly affixed CE Marking, and unlawful if distributed in the UK.
>
> 8. As a consequence of the breach of Contract, DHSC cannot use the Goods in the NHS.
>
> Rejection of the Goods
>
> 9. In light of the above breach of Contract, DHSC rejects all the Goods purchased under the Contract in accordance with Schedule 2 clause 4.2 and/or 4.6 of the Contract (Rejected Goods)".

166. On 11 February 2022 DHSC sent a letter before action to Medpro, outlining its claims on the basis that Medpro did not have the relevant CE accreditation or a derogation, as a result of which the gowns could not be used.

Testing of Gowns

167. Over the course of 2022, DHSC procured sterility testing on 120 gowns from Swann-Morton (Microbiological Laboratory Services) Limited ("Swann-Morton") and 20 of the gowns from Synergy Health Ireland trading as Steris Laboratory Tullamore ("Steris").

168. On 27 April 2022, 6, 15 and 22 June 2022, as well as 12 and 22 September 2022, Swann-Morton test result certificates for the anaerobic sterility testing were obtained. Further test certificates were obtained by Swann-Morton on 6 (on which date there were two) and 13 October 2022. On 30 May 2022, DHSC sent a further letter to Medpro explaining that "*As part of broader testing of PPE products that DHSC has been unable to use, DHSC commissioned sterility testing of a sample of PPE Medpro gowns by Swann-Morton (Microbiological Laboratory Services) Limited*". The letter set out some preliminary test findings showing that 26/30 gowns were not sterile. The letter identified further breaches of the Contract in light of that evidence.

169. The first tranche of 60 gowns tested by Swann-Morton between April and June 2022 resulted in 26 out of 30 gowns failing the aerobic test and 29 out of 30 gowns failing the anaerobic test. The second tranche of 60 gowns tested between August and October 2022 resulted in 26 out of 30 gowns failing the aerobic test and 22 out of 30 gowns failing the anaerobic test.

170. Microbes were isolated from these tests and sent to another laboratory ("Charles River") for detailed microbiological identification. On 11 July 2022, Charles River Associated provided the first tranche of the results of their microbiological testing, and on 13 October the second tranche.

171. A third lab, Steris, also carried out (less detailed) microbiological identification between 23 and 30 November 2022. Their certificate was issued on 15 December 2022. The sample for the microbiological identification test report was received on 22 December 2022, and approved on 13 January 2023. Of those 20 gowns, 19 were found to be not sterile.

The Trial and issues

172. The trial has been conducted over 13 days of court time. As matters transpired evidence on many of the issues was rather less lengthy than had been anticipated at the time even of the PTR and the time set down for trial erred on the side of generosity.

173. In line with this Court's practice, the parties were invited to give active consideration to providing opportunities within trial for meaningful junior advocacy. That invitation was responded to in an exemplary fashion, with all junior counsel being offered a chance to call or to cross examine witnesses in the course of the trial. Notably, for example, a number of the less contentious factual witnesses were called and cross examined by junior counsel: Mr Horkan and Mr Reid (Sampson/Cukier), Mr Bates (O'Neill /Cukier), Ms Naeem (Sampson/Breslin). Further excellent courteouly probing cross examinations of Dr Williams and Dr Popovic were conducted by Mr Cukier and Mr Sampson respectively.

174. Owing to the nature of the issues and the absence of factual evidence from the Defendant's side, it is best to consider the evidence in situ – in relation to the issues to which it was relevant. However in summary all of the witnesses in this case, factual or expert, were honest witnesses who were in my assessment doing their best to assist the court to resolve a rather unusual case.

THE CONTRACTUAL CLAIM

Introduction

175. The basic principles of construction do not need extensive discussion. As is to be expected, reference was made to the current core trinity of cases: *Rainy Sky SA v Kookmin Bank* [2011] UKSC 50 at [21] (per Lord Clarke), *Arnold v Britton* [2015] UKSC 36; [2015] 2 WLR 1593 at [15]-[23] (Lord Neuberger) & [76]-[77] (Lord Hodge) and *Wood v Capita Insurance Services Limited* [2017] UKSC 24 at [9]-[15]. A little variety was offered by reference to useful summaries by HHJ Pelling KC and approved by the Vos C in *Lamesa Investments Ltd v Cynergy Bank Ltd* [2020] EWCA Civ 821, 2021 2 All ER (Comm) 573 at [18] and *ABC Electrification Limited v Network Rail Infrastructure Limited* [2020] EWCA Civ 1645, at [18 (ii)].

176. However the issues between the parties did not require reference to these principles, but were more about how the specific contractual structure worked and which bits, if any, required to be read down.

177. There are a number of points of construction which are in dispute. These can be summarised thus:

    a. Did the Contract require Medpro to follow a validated process demonstrating that the gowns when delivered should be sterile to a sterility assurance level (SAL) of 10^{-6};

    b. Did the Contract require Medpro to follow a process, consisting either of the application of BS EN 556-1:2001 or an "equivalent technical solution" to the manufacture and sterilisation of the gowns?

    c. Did the Contract require Medpro either to apply a valid CE mark to the gowns, or to have obtained a derogation pursuant to Regulation 12(5) of the Medical Devices Regulations 2002 ("MDR 2002") for the gowns?

178. It is fair to say that the first of these issues has only taken full form during the course of trial. However it was not, at least initially, suggested that this question was not capable of being fairly decided based on the evidence which was before the Court. While Medpro in closing somewhat resiled from its earlier acceptance of the issue as live, it is, though unpleaded, a point which was squarely raised by the start of trial and would have been explicitly pleaded had Medpro objected earlier. In addition (and as reflected by Medpro's initial reaction to it) it is not an issue which would have caused prejudice such as to make it appropriate to shut the issue out. Accordingly that issue is considered below.

The parties' cases on construction

179. The starting point here is the complexity of the contractual documentation, which offered scope for the rather different approaches of the parties.

180. As already noted the Contract was comprised in a number of documents. Section 5 of the Order Form and Schedule 1, clause 2, set out an order of priority for construction purposes, to apply if there was a "conflict" between different provisions:

    a. The Order Form, including in order of priority:

        i) the Authority's requirements in the form of its specification and other statements and requirements;

        ii) any clarifications to the Supplier's responses, proposals and/or method statements;

        iii) the Supplier's responses, proposals and/or method statements;

    b. Schedule 1: Key Provisions;

    c. Schedule 2: Terms and Conditions;

    d. Schedule 3: Definitions and Interpretations;

e. Any other documentation forming part of the Contract in the date order in which such documentation was created with the more recent documentation taking precedence over older documentation to the extent only of any conflict.

181. DHSC predictably rests heavily on the terms set out in some detail in Schedule 2, which plainly signpost the applicability of the relevant legislation on medical devices, including CE marking and EN 556. Medpro however highlights the ETRD and the Key Provisions, against the backdrop of the EC Recommendation as well as the wider factual background including the crisis created by the pandemic and the DHSC's ability to apply for a derogation. While accepting the existence and *prima facie* effect of the extensive references to incorporation of relevant legal standards it argued that that (i) the ETRD as the "specification", (ii) the absence of specification for a CE mark in sections 6 and 7 of the Order Form, (iii) the reference only to EN 13795, and (iv) the absence of full (notified body) CE numbering in the photos in the Annexes means that insofar as Schedule 2 terms would require CE marking or compliance with EN 556, those provisions were not, on the true construction of the contract, part of the agreed terms.

182. This conflict is therefore the route to the issues identified above. As to the first of those issues, Medpro says that the same points lead to the conclusion that there was no independent contractual obligation to demonstrate a validated process.

183. At the same time as the existence of those issues there is significant common ground, in that Medpro accepts that on its true construction the Contract required that the gowns, when delivered, "*should be sterile to a sterility assurance level (SAL) of 10^{-6}, i.e. that no more than one in a million gowns should not be sterile."* As explained below, on its own case what Medpro really means by this is that the gowns were required to have a SAL of 10^{-6}. As it put it in opening submissions: *"[Medpro] accepts that it was obliged under its equivalent technical solution … to provide gowns to a SAL of 10^{-6}"*. What is does not accept is that *"there was any independent contractual obligation to demonstrate a validated process".*

184. This point, as to a contractual obligation to provide gowns with an SAL of 10^{-6} is plainly rightly accepted. The route to contractual construction which Medpro explicitly accepts and advocates is via the ETRD. This was the document identified as "the specs" which it says it relied on. It is also the document with which Medpro had to comply pursuant to Schedule 1, clause 2.2. As noted above the ETRD made clear the SAL requirement.

185. It is therefore only necessary to note in passing that other routes to this same requirement could be taken, depending on the view which is taken of the contractual hierarchy of materials and what fits within it. This could be via any of the following:

a. as an aspect of fitness for purpose (Schedule 2, clause 7.1.1) and/or s 14(3) of the Sale of Goods Act 1979;

b. as a requirement if the gowns were to meet their description (Sale of Goods Act 1979, s 13);

c. as an aspect of the requirement of satisfactory quality (Sale of Goods Act 1979, s 14(2));

d. pursuant to Schedule 1, clause 12;

e. pursuant to Schedule 2, clause 7.2.

The significance of the accepted obligation to deliver gowns with an SAL of 10^{-6}

186. Medpro would say that its acceptance of the SAL requirement is peripheral. That is not an approach with which I can concur, for the following reasons.

187. As already noted, any assessment of SAL is based on the demonstration of the absence of growth of any viable micro-organism following a sterility test. The earlier part of the judgment has outlined the main standards in play.

188. What is notable about the standards is that none of them provide a regime for testing individual sterile medical devices (here gowns) to establish their sterility. That is because it is not possible to know whether a product is sterile by inspection or non-destructive testing. Neither sterility expert suggests otherwise. Nor is it feasible to test gowns after they have been packed and sterilised in order to confirm that the packaged products are sterile to a SAL of 10^{-6}.

189. This is because a Sterility Assurance Level, as the nomenclature implies, does not (even conceptually) describe a physical or testable characteristic of any individual gown. The physical quality that each gown has is that it is either sterile or not. The SAL takes a different approach – it expresses sterility as a probability of finding, via specific testing, a single micro-organism on a sample product after sterilisation of the sample, and before the relevant contractual goods are sterilised. By its nature one cannot test for a probability.

190. But putting that aside for the moment, if the requirement were slightly different - a requirement for no more than one gown in X to produce (on the appropriate test) any microorganism, it would be possible to test after the event only by testing a population. At the level of probability involved this is plainly not feasible as was noted in the expert evidence. If the standard were, say 10^{-1} (one non-sterile gown in 10), that standard could potentially be verified by considering a reasonably small sample. But using a SAL of 10^{-6} means that to prove compliance positively would mean testing millions of gowns. It could not, even theoretically, be done without opening the packages of vast numbers of gowns, and thereby compromising their sterility and rendering them useless.

191. Reverting then to the conceptual difficulty of testing for a probability, the question which arises is how, on Medpro's case, contractual compliance with this key requirement can be ascertained.

192. One possibility (which was effectively advocated by Medpro as the answer in this case) is that on the true construction of the Contract the parties agreed up front that the SAL of the 25 million gowns not yet manufactured was conclusively established by the documents provided (and scheduled to the Contract as Annexes). That is the correlate of Medpro's submission that *"it was, therefore,*

for the DHSC to specify and approve the documents that it required and would accept as sufficient to validate that the gowns were sterile with a SAL of 10^{-6}".

193. That is a proposition which cannot be accepted. That is not, on any analysis, what the Contract says. The Annex itself does not present that way: it is called "Technical Specification" and lists different documents for the two factories covering photos as "Packaging Specification", test certifications, certificates and declarations of conformity and QMS certification. The relevant Annexes for WTT comprise a declaration of conformity explicitly for a non-surgical gown and an ISO 13485 certification.

194. But also in drafting terms, there would in fact be no point in incorporating any SAL requirement at all, if this were the agreement: the sensible course would be to contract for gowns manufactured by WTT and complying with the Annex 1-4 documents. This would be somewhat akin to the kind of conclusive evidence or binding determination clause which is not infrequently encountered in dealing with large amounts of more conventional cargoes – as referred to by Dr Williams who accepted that a possible approach might be acceptance testing by a smaller sample, akin to the approach in more conventional sale of bulk goods cases. However even in such a situation one would expect a clear regime for this – and that is even where acceptance testing might be a closer approximation to proof of compliance. In this context not only would this approach not be sensible, it runs contrary to the usual principles of construction to reach a conclusion that this uncommercial approach was intended, particularly where it would (as Medpro accepted) require the "reading down" (ie striking through) of considerable tracts of the contractual terms.

195. Much argument was addressed to derogations and "equivalent technical solution". They add nothing to this point; when it comes to SAL the solution which Medpro say was agreed is not equivalent, because it does not comply with the essence of SAL. The truth is that if the pre-contractual discussions between the parties (combined with the "covid crisis" background) have any effect it is not via the proof of SAL being thus specified. That is not to say that these points may not feed into the other construction arguments (so far as relevant) as well as the various estoppel arguments or rectification arguments relied on by Medpro.

196. If it is the case that the contract does not say that the Annexes establish that on the true construction of the Contract the gowns manufactured will be sterile to SAL 10^{-6}, how can the SAL requirement be established (or established not to have been complied with)? This takes one back into the concept of a sterility assurance level. The experts here were essentially agreed. As Mr Atchia put it*: "Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method"* and the *"manufacturer is obliged to define an appropriate standard and then ensure that it is fully validated"*.

197. On the evidence the base standard in this regard is ISO 11137-1. As can be seen from the introductory section that standard contains a number of steps. Mr Atchia explained them in his first report:

    a. Establishing a suitable process (accepted to be ionising radiation): as set out in ISO 11137: 1;

b. Dose-setting: Method 1 ISO 11137: 2 via Table 5 (which involves taking into account the microbial contamination level or "bioburden" of a test article and validating a dose based on the bioburden);

c. Execution of sterilising method: ISO 11137: 1 (appropriate setting up of the radiation equipment to ensure that the right dose is delivered to every gown, and delivering the sterilisation dose). As Mr Atchia put it*: "The overall sterilisation process must then be qualified. This is usually achieved empirically, by reference to the steps set out in sterilisation process standards under the term of process performance qualification. Under the standard EN ISO 11137-1 this will typically include: a dose map; minimum and maximum dose location and magnitude; minimum and maximum dose relation; and recommended routine sterilisation (or sterilising) dose."*

198. Those stages reflect his evidence orally that the standard is *"used to develop, validate and routinely-control an ionising radiation sterilisation process"*. Mr Atchia went on to confirm that such a typical 'standard' is necessary to *"demonstrate and document SAL"*. This is reflected also not just in the structure and wording of ISO 11137 itself, but also in the wording of the key line in the ETRD: *"Must be **validated** as sterile – with Sterility Assurance Level (SAL) of 10-6"* (emphasis added).

199. This too was the evidence of Dr Richards, which was that with sterile medical devices the limitations and difficulties of sterility testing after the event meant that it is important in the ordinary run of things to have a validated process. In addition, the evidence of Dr Williams (in line with what has been said above) was that the statistical difficulties meant that *ex post facto* testing was not feasible and that different approaches had to be adopted and the first one that he pointed to was this approach *"that people actually look at the process and audit the process…"*.

200. Thus necessarily SAL (certainly at this level) requires the following of a process which has stages and each of those stages is defined by ISO 11137; and it requires validation of that process having been followed (or the systems which ensure that it is to be followed) in the form of documentation of the process. This "validation" of course dovetails precisely into the "assurance" aspect of SAL.

201. It follows that the logical correlate of Medpro's acceptance of the obligation to produce gowns with an SAL of 10^{-6} is that compliance had to be tested via the process and the validation of that process. To that extent DHSC's "new" case as to "validated process" merged into Medpro's concession. There may not have been an independent contractual obligation to demonstrate a validated process, but that requirement of a process was inherent in the SAL requirement which Medpro must and does accept.

Was there breach of a requirement for a formally validated process in this case?

202. There was then a distinction between the parties as to whether the Contract required a formally validated process (ie via compliance with BS EN 556-1:2001 and CE marking or similar); this was the DHSC's primary case. Another possibility, tacitly advocated by Medpro's case on contractual construction (and

effectively accepted in practical if not contractual terms by DHSC) is that it would potentially be possible to establish compliance by providing documents which established either that the gowns had undergone a process covering all relevant stages, or that they had separate certifications to cover all the constituent parts of the sterility assurance process (ie some form of ongoing audit of the sterilisation process).

203. As regards this point only (and ignoring the other construction arguments) this seems a perfectly reasonable approach. In other words, one method of establishing SAL compliance, if that were the only question, would be for the person in the position of Medpro to produce a sheaf of individual certificates documenting each stage of the process. This is similar to but not identical with the provision of an ISO 11137 Part 1 certificate (which did occur here). It is not identical because each part of the process must be documented. It is not enough to certify one part if the others are not also vouched for. Achievement of the requisite SAL can be derailed by not properly establishing a sterilisation dose, or by (while knowing the right dose) not validating it to ensure consistency or by not applying it properly either at all or over time.

204. This approach also partially merges into compliance with EN 556-1; because that is done via a CE marking with a notified body number, but the ability to add a notified body number equates to saying that A+B+C+D have been established by the means set out in the standard. Thus I conclude that an appropriate SAL could equally be proved by producing the individual evidence for A, B, C and D.

205. However that does not answer the question of whether there was compliance with validation requirements as to SAL in this case. The answer to this question is a clear no. This result can be arrived at by a short route or a longer one.

206. The starting point is via the experts' joint statement. The sterility experts' Joint Report agrees, at paragraph 2.1, that *"information normally required to demonstrate a fully-documented performance qualification as expected by EN ISO 11137-2 (and EN ISO 11137-1) was not provided"*. In a sense that answers the question; but since it theoretically leaves open the possibility that there is nonetheless evidence, though not that "normally required" which can demonstrate a fully-documented performance qualification, it is necessary to interrogate the stages involved.

207. The short route from here is to ask whether there is evidence of dose setting by an appropriate method (the defined methods in BS EN ISO 11137-2:2015 or any other method). It is common ground that there is no such evidence.

208. The longer route is to consider what there is. There is what was referred to as "the Dasheng Report" (there were no reports for other irradiators). That document has sections dealing with responsibility, procedure, preparation, dose mapping, dose measurement and batch processing, but not dose setting. Importantly, it notes as follows:

> "The customer shall provide the sterilization dose specification and 3 units of product.

> The QC Department .. shall determine the loading pattern of products, in order to get a fine uniformity of dose distribution in products and obtain the maximum efficiency of radiation processing. According to the DOSE SETTING from customer, formed the PQ protocol, including the dosimeter position, the quantities and process parameters."

209. In other words, Dasheng does not purport to do all the stages of ISO 11137-2. Critically it does not purport to do the complicated dose setting process outlined above, but relies on the customer to stipulate a dose. Dasheng would take the dose and test only to ensure "*a fine uniformity of dose distribution*".

210. There are also irradiation certificates. These are a record of the doses of irradiation that have been applied to the gowns; some express the doses as the minimum and maximum applied as compared with the specification, some express the applied dose as an average dose, and some state only the minimum absorbed dose (not the maximum). These also suggest the dose was set by the customer (WTT).

211. Mr Atchia in his first report annex stated it is *"unknown how these maximum and limits were established"*. While Mr Atchia and Medpro's legal team urged an inference that obviously the irradiators would have done dose setting first, and no reputable company would do otherwise (see Mr Atchia's evidence that no company that he had ever audited, inspected or assisted would have conducted the Dasheng dose calibration experiment without first conducting sterilising verification dose exercises) (i) inference is not validation and (ii) that inference is, on the facts of this case, plainly unsafe when taken against the actual evidence from the reports from Dasheng which indicated clearly that "*The customer shall provide the sterilization dose specification*" and the fact that the irradiation certificates appear to show doses having been set by the customer.

212. The result is that what there is leaves a glaring gap: as Dr Richards said there is no *"microbiological qualification of the irradiation dose and all we refer to is a statement that the textile company is providing an assurance that an [sic] SAL to the minus 6 is achieved with no supporting data…"*

213. That segues into the next aspect of the failure: bioburden and its impact on the right dose. It is fairly obvious (and clear from ISO 11137: 2 Table 5) that the amount of irradiation needed will depend on how dirty the items are – or in technical terms how much of a bioburden there was. Mr Atchia accepted in his reports that there must be a process which can be validated to demonstrate and document SAL, which will include analysing the bioburden.

214. However, there is no documentation to show that the bioburden of the gowns was assessed as part of a dose-setting exercise. As Dr Richards said there is no "*microbiological qualification of the irradiation dose…"*

215. There are some records of microbial cleanliness, but they were produced for the purposes of other inspections, not as part of any dose-setting exercise. Mr Atchia accepted that was the case. It was noticeable that (i) Medpro steered entirely clear of the concept of bioburden except as regards the ex post facto testing and what

could be inferred from it and (ii) Mr Atchia was driven to attempt to work backwards to a conclusion. He performed an exercise of inferring what that bioburden was by working backwards from an assumption that the sterilising dose is correct and using the information contained in Table 5 of EN ISO 11137-2:2015. He then sought to support the calculation by relying on the limited cleanliness and bioburden data available from tests conducted on the gowns by Intertek and GTTC as part of their manufacture. However, as became clear in cross examination, this approach was not helpful to Medpro. It became apparent that Mr Atchia had misunderstood the figures given in the Intertek and GTTC reports – and that as a result the figure he was using was understated by a factor of 100.

216. The more accurate analysis (albeit one with which the experts were not entirely happy) proceeds thus:

    a. The figures given in the tests carried out by GTTC and Intertek are for between 14 and 77 cfu per $100cm^2$ (average 40.35);

    b. This correlates to a conclusion that the bioburden on the tested gowns was between 6,000 and 9,000 cfu;

    c. Adopting the Table 5 approach suggests that a dose of between 27.8 and 28.5 kGy would be required to achieve a projected SAL of 10^{-6}.

217. On that basis *prima facie* irradiation would not have achieved the requisite SAL at the level of irradiation which the manufacturers stipulated for with the irradiators (where there is evidence, it was from 18.2 kGy to 20.3 kGy).

218. Accordingly on the true construction of the Contract there was a requirement for a validated process; and in breach of the Contract there was no validated process. The evidence which there was did not establish two key parts of the process had been undertaken: bioburden testing and dose setting.

219. Subject to questions of estoppel, therefore, liability can be established at this stage.

Did the Contract require EN 556 or an Equivalent Technical Solution?

220. That means that technically speaking, it is not necessary to establish the answer to this question.

221. However, for clarity it is neither here nor there that the only EN standard with which the Contract explicitly required compliance was BS EN 13795-1:2019, that this was the only "EN#" checked in Section 6 of the Order Form, and it was the only quality assurance standard referred to in paragraph 3 of Schedule 1. Nor does it matter that Medpro never provided documents demonstrating compliance with EN 556-1, or that it was Mr Graham's evidence that the Technical Team had advised him directly that the standard with which the gowns were required to conform was EN 13795-1:2019.

222. Equally there is no need (as DHSC sometimes suggested) to see the reliance on the ISO 11137:1 certificate as evincing an intention to comply with EN-556-1. Medpro is right, and DHSC's witnesses accepted that that ISO 11137 was different to, and did not constitute compliance with, EN-556-1. ISO 11137 gave a route to a validated process for the relevant SAL. EN-556-1 defines the SAL often used for medical devices.

223. However, the Contract explicitly (and independently of EN-556-1) required SAL 10^{-6}. The Contract required a validated process relevant to establishing SAL 10^{-6}. That is, in essence, what EN-556 required. To the extent that EN-556 required more than these two elements, there might be scope for saying that EN-556 was not required -not least because, as Medpro have repeatedly said, the contractual documentation only referred to EN-13795 as the required EN standard.

224. When one looks at EN-556, there is, as noted above, essentially nothing else of relevance. Accordingly, this question could be answered in two ways: no, EN-556 is not required (separately or distinctly); alternatively the main planks of EN-556 are indeed required via the prior issue. And, specifically, and contrary to Medpro's submission in closing on the true construction of the Contract Medpro was required to comply with paragraph 4.1 and 4.2 of EN-556-1:

> "4.1 For a terminally-sterilized medical device to be designated "STERILE", the theoretical probability of there being a viable micro-organism present on/in the device shall be equal to or less than 1 : 10 -6
>
> 4.2 Compliance shall be shown by the manufacturer or supplier through provision of documentation and records which demonstrate that the devices have been subjected to a validated sterilization process fulfilling 4.1."

Did the Contract require CE marking?

225. In the premises, this point is not determinative. For completeness however, so far as this is concerned there is a tension between the parts of the Contract on which DHSC relies and the passages which Medpro emphasise.

226. Medpro are right to say that:

a. The Order Form took precedence in the event of any conflict with other provisions in the Contract;

b. Section 6 of the Order Form left the box titled "CE#" blank. That is certainly consistent with a case that the gowns would not have and therefore did not need a "CE#";

c. Section 7 of the Order Form is also consistent with that. It provided that "*specification of the Deliverables*" was as set out in the Annex and the photographs within the Annexes did not include an NB number and Medpro never provided a picture of a valid CE mark (or any valid CE mark number for the WTT supply).

227. However to some extent that case as advanced was at odds with its own pleaded position. The emphasis on the photos was not consistent with its earlier view that the photographs in the Annex did not form part of the Contract, and the parties had "*not in fact reached any agreement as to what the 'Packaging specification' should be"* and "*were at most intended to illustrate only that the said gowns would be wrapped and boxed in a way which was sufficient to permit the irradiation of the said gowns and maintain their sterility (subject to proper transportation and storage of the same by the Claimant and/or its servants or agents)"*.

228. Ultimately the sheer weight of provisions within the Contract which required compliance with the applicable laws (and the consequent extent of "reading down" called for) would in my judgment outweigh (i) the indications to be gleaned from the failure to specify CE marking on the Order Form (which are not clear, but ambivalent), and (ii) the obviously in some respects inaccurate photos (the WTT photos indicated show a product that was intended to be sterilised by ethylene oxide rather than by irradiation). All of the following provisions point to a requirement for CE marking:

    a. Schedule 1, clause 12.2 (obligation to comply with the Medical Device Regulations);

    b. Schedule 2, clause 1.1.6 (obligation to supply the goods "in accordance with the Law");

    c. Schedule 2, clause 7.1.9 (obligation to "comply with all Law");

    d. Schedule 2, clause 7.2 (obligation to comply with "Law and Guidance" relating to medical devices, and warranting that the medical devices would have valid CE marking or Product Authorisation);

229. Furthermore Regulation 10 of the MDR 2002 is clear and explicit as to the need for a CE number. There was no discussion between the parties as to use or otherwise of a CE number – and the WTT pictures did show a CE mark, just not one which was apt for sterile products. The use of the "non-sterile" CE marking would be a breach of the law, and it would be nonsensical for the parties explicitly to contract for that outcome.

230. Accordingly to the extent necessary I would conclude that on this point DHSC also had the better of the argument, and CE marking was required.

The original case: Statistics, Physical Testing and Sterility

231. The original formulation of the case in contract was much less focussed on construction and far more on expert evidence. That is the case based on the 2022 testing of the gowns; the case being that the testing results prove that the gowns did not meet the contractual SAL. In the light of the conclusions above it is both analytically peripheral and, on the findings made, a question which does not arise. Accordingly it is dealt with in Annex 1 to the judgment in relatively brief terms.

ESTOPPEL AND RELATED CONCEPTS

232. The next stage of Medpro's case was that if the Contract, on its true construction, did require more than was delivered, DHSC nonetheless was estopped from relying on the relevant clauses which imposed those obligations. In other words it said that DHSC was not entitled to rely on the relevant contractual terms because some combination of what was said or done or believed rendered it unfair to do so. Medpro's case was pithily summarised in its written closing thus: *"[Medpro] provided the documents it had. DHSC approved the Contract based on those documents. That was a clear representation that PPEM's offer met the applicable requirements; DHSC cannot now assert that they did not."*

233. This case went primarily to the EN 556 and CE marking aspects of the contractual case, and those are considered first.

234. Estoppel, of course, is not a generalised "mop up" concept to be applied in any case of perceived unfairness. It is the umbrella concept which links a number of distinct doctrines or rules – each with their own requirements. It is therefore necessary to be clear, in any given case, exactly which doctrine is relied upon, what the requirements of that doctrine are and how the distinct requirements are satisfied.

235. Medpro relied generally on contractual estoppel, estoppel by representation, estoppel by convention, estoppel by acquiescence. Although contractual estoppel was less in focus by closing, it continued to rely on the others somewhat globally, with the applicable doctrine depending on how the court interpreted the evidence which had emerged.

236. That being the case, it is worth commencing with an overview of what is involved in each of these concepts.

    a. Contractual estoppel is conceptually distinct (as both parties really agreed – Medpro by its location within the skeletons). Contractual estoppel is all about holding a party to the terms of its contract (see Foxton J in *Rolls-Royce Holdings plc v Goodrich Corporation* [2023] EWHC 1637 (Comm) at [47]). Therefore if Medpro is wrong on contractual construction, contractual estoppel offers no life line.

    b. Estoppel by representation has the following elements (see *Chitty on Contracts* 35th ed. paragraphs 7-006-7-011):

        i) Clear and unambiguous representation;

        ii) At least objective intention by representor that the representee will rely and that reliance should be reasonable[1];

        iii) Actual reliance in fact;

[1] This "parks" the fascinating but contentious question of "active presence" in the representee's mind. In the current case this is an unnecessary complication.

iv) Prejudice/detriment if the representor is allowed to rely on the representation.

c. Estoppel by convention has the following elements (see Chitty paragraphs 7-016-7-028):

i) Both parties are involved in an assumed state of the facts or law;

ii) That assumed state is unambiguous or clear;

iii) The assumption must be shared and there must be words or conduct which crosses the line between the parties from which the necessary sharing may be inferred;

iv) Both parties act on that assumed state of facts or law and specifically the party asserting it must in fact have relied upon the common assumption, to a sufficient extent, rather than merely upon his own independent view of the matter;

v) Prejudice/detriment if one party is allowed to rely on the real (non-assumed) facts/law.

d. Estoppel by acquiescence (in the sense relied upon by Medpro[2]) has the following elements:

i) One party to a transaction has made an assumption as to the state of facts or law;

ii) That assumed state is unambiguous or clear;

iii) The party estopped knew of the understanding adopted by the other and acquiesces in that assumption;

iv) The party asserting it must in fact have relied upon the common assumption, to a sufficient extent, rather than merely upon his own independent view of the matter.

237. It can therefore be seen that there are certain elements which are common to most of the concepts prayed in aid by Medpro. In particular all of the estoppels cited require (i) some form of clear representation or assumption and (ii) the party invoking the estoppel to prove reliance in fact, and its correlate prejudice/detriment.

238. These two elements require some consideration.

[2] Mainly based on ABN Amro Bank NV v Royal and Sun Alliance Insurance Plc [2021] EWCA Civ 1789 [2022] 1 WLR 1773.

Representation/assumption: clear?

239. The first question is to ask what was represented or assumed. Medpro argues that the representations/assumptions are four fold, namely that:

    a. DHSC had approved Medpro's equivalent technical solution,

    b. It was for DHSC to apply for a derogation,

    c. Medpro met the necessary technical requirements including in particular as to CE-marking,

    d. Medpro was not required to supply gowns with a valid CE mark accompanied by a NB number.

240. Overall however they can be divided into two: (i) representation/assumption re "equivalent technical solution" (no EN 556) (ii) representation/assumption re no CE mark with notified body.

Approval of an ETS in place of EN 556

241. Medpro's case was stated in its written opening, that DHSC expressly (alternatively impliedly) represented that this was the case by Mr James's email confirming approval and this was also conduct that crossed the line for the purposes of estoppel by convention, creating or confirming the parties' common assumption (objectively construed) that the equivalent technical solution was approved.

242. Medpro indicated that the representation/assumption arose from the following:

    a. DHSC had specifically requested that Medpro provide certification in relation to EN 556-1, which was never provided;

    b. The gowns were then approved by Technical. The approval by Technical therefore cannot have been on the basis of the EN 556-1 solution. It follows that, objectively construed, approval must have been on the basis of an equivalent technical solution;

    c. When first asked for the EN 556-1 certificate, (in addition to seeking clarification as to the certification requirements) Mr Page asked for the ISO number which was equivalent;

    d. As the final certificate provided by Mr Page certified compliance with ISO, it was logically this "equivalent" standard that was approved;

    e. It was obvious to both parties that the existing documentation did not include any EN 556-1 certification. In those circumstances, when Mr James asked where the SAL was confirmed he must have been asking whether the SAL could be confirmed by an alternative document – i.e., an equivalent technical solution;

f. Thus, Technical's approval was on the basis of an equivalent technical solution. Moreover, this representation was confirmed and repeated in Mr Graham's passing on to Mr Page the fact that Technical had approved the Medpro submission.

243. I do not accept that any such clear or unambiguous representation or assumption can be spelled out of this material, taken against the full context. There was an exchange where Mr Page was obviously wrong in saying that what was needed was EN 13795 or EN 556 and that Medpro was fine because their supplier could do EN 13795. Mr James clarified – and gave a contextual explanation that what was needed was something which showed the ability to comply with the SAL (which EN 13795 did not). To this Mr Page replied with the ISO 11137:1 certificate – which demonstrated compliance with some parts of a quality assurance system capable of producing sterile goods. Things were happening at some speed and not everything was spelled out. After this DHSC indicated that "*gowns approved by technical*". After that the full Contract terms were sent, some days in advance of agreement.

244. Was there an unequivocal representation that EN 556 was not needed because an ETS was agreed? While it may be the case that Mr Page (who appears not to have been very familiar with the relevant standards) may, subjectively, have believed that he was being told that what he had provided was enough to satisfy compliance with the requirements, if he did so (and of course there was no evidence from him that he did so understand the exchanges) he did not do so because there was objectively any clear statement or basis for assuming that (i) the ETS process was engaged (ii) that a derogation had been sought or (iii) that an ETS had been approved. There was no mention of an ETS in any of the relevant communications. Nor was there a clear representation that EN 556 was not required.

245. The ETS route had been suggested (as an undesirable route) earlier on in the discussions. In another contract it had been positively engaged with and specifically discussed. Here there were no explicit indicators of following this route. Further the immediate backdrop to the "*Gowns approved by Technical*" was a series of exchanges about whether the material provided grappled with the question of SAL; and Medpro was not saying "*yes, but by another route"*. Medpro was repeatedly assuring DHSC that they were certain they could comply with the requirements provided to them: *"we always deliver 100% quality and on time"*. If anything objectively Medpro was asserting compliance.

246. It is worthy of note that Medpro have never been entirely clear about what the ETS agreed was: was it 11137:1? Or was it "*what the Annex says*"? Nor could Medpro ever address how either of these were equivalent. The only possible way an equivalent technical solution could come into the picture was via the reference to ISO 11137; but objectively in the discussions Medpro appeared to rely on this as evidence of compliance with EN 556. Further if equivalence were objectively being asserted it would need to be a functional equivalence, which this was not. If Medpro properly understood the nature of sterility and the requirements of sterile gowns it would have appreciated that all it had supplied went to manufacturing standards, not to the question of sterility at all. ISO 11137 is not about how to designate a medical device as "sterile". That is what BS EN 556 is

for. ISO 11137 is about the requirements to develop, validate and routine control a radiation sterilisation process. In terms of process, it comes, logically, before BS EN 556—not instead of. Indeed, ISO 11137 also refers to BS EN 556 at various times, further demonstrating that BS EN 556 is very much not the same as ISO 11137, e.g.: "*Attention is drawn to regional and national requirements for designating medical devices as 'sterile'. See, for example, EN 556-1 or ANSI/AAMI ST67*". In that context there was no equivalence and no-one understanding the area could have understood a representation in that sense.

Meeting the technical requirements/ No requirement to have a CE mark with an NB number

247. This is where the case engages most clearly with the exchanges. Medpro relies on the "*gowns approved by technical*" statement, against the background of the process of submission, as a clear and unequivocal representation. But even so and taken against the background, this falls some way short of the unequivocal or clear representation or basis for assumption which would be needed. The statement does not itself say what is relied on or mention CE marking. And any representation has to be placed against the wider background (including as to sterility), the structure of the process and Medpro's knowledge of the process (i.e.) that the contracts stage needed still to be completed). On this basis at best this statement can be taken as an implicit representation that the DHSC considered that the material suggested that the gowns were capable of meeting technical requirements. Such a requirement is itself so vague that it could not found any estoppel.

248. Further, to the extent anything could translate into a representation/assumption, there is nothing which could make a clear representation/assumption about CE marking. Medpro's case was that:

    a. It is common ground that Medpro never provided and never purported to provide a valid CE mark with a NB number for the sterile gowns manufactured by WTT.;

    b. Mr Page's email sending the ISO certificate was preceded by an email stating *"We are certain that we are 100% compliant"* and was accompanied by the comment "*Hopefully this is all your technical department requires*";

    c. The response was an approval by Technical and Mr James's confirmation that "*Gowns have been approved by Technical!"*

249. This is said to be the basis for a clear and unequivocal representation that there was no requirement to have a CE mark with an NB number. As Mr Samek KC put it in closing: *"it is obvious what is implicit in that, that DHSC were satisfied with everything that we had given them and that's why we passed on to the next stage and they sign the contract. No valid CE mark was therefore required. No need to demonstrate anything else."*

250. That expansive statement of what is sought to be read into the terse one liner needs only to be stated to be seen to be wrong. Nor can it be said that one can get to an unequivocal representation/assumption via an argument that: Medpro was

"100% compliant"/ therefore Medpro had provided everything that DHSC required/ therefore no need for an NB number. The short point is that the absence of an NB number in the photo was at least equally consistent with the photo showing a blank pro forma, which would have the producer's own NB number applied. There is simply not enough explicitness or enough absence of alternative meanings for a clear representation/assumption to be the result.

Reliance

251. This is a point of some significance here, because Medpro elected not to call any factual evidence. This is the conventional way of proving reliance: tendering a witness who says *"we would not have committed to this contract if we had not been told X/understood Y."* – and is then tested on that and on whether (in the case of estoppel by representation) such reliance was reasonable: *Jones v Lydon* [2021] EWHC 2321 (Ch) [61]; *Canada and Dominion Sugar Company Limited v Canadian National (West Indies) Steamships Limited* [1947] AC 47 (PC), 56. In the case of estoppel by convention the evidence must be tested on the extent of the reliance – whether it is to a sufficient extent or rather on the witness's own independent view of the matter: *HMRC v Benchdollar* [2009] EWHC 1310 (Ch) [52].

252. Here the obvious witness was either Mr Page or (possibly) Mr Barrowman. The first of these conducted the negotiations on the ground and signed the contract. There was no explanation of why he was not called. The latter appears to have been the economic principal of the business. Notably he attended court throughout the trial and plainly could have been called.

253. In some cases it is possible to avoid the need for hazarding a witness on this issue – if it is a case where there is clear internal documentary evidence of reliance and detriment. This is not however what Medpro has done here. Rather it asserted in its written opening: *"It is plain that Medpro procured the supply of the gowns on the understanding that they met the applicable requirements"*. That was plainly not a realistic case.

254. In conventional terms therefore Medpro cannot prove reliance.

255. In its written closing, Medpro shifted ground to arguing that that the position is akin to inferring reliance from materiality in insurance disputes. It submitted that the representations or assumptions were all highly material. They went to the heart of Medpro's offer, its approval, and therefore what Medpro was required to supply.

256. In oral closing this was backed up by reference to *Dadourian v Simms* [2009] EWCA Civ 169 citing Arden LJs dictum at [99] that:

> "1) it is a question of fact whether the representee has been induced to enter into a transaction by a material misrepresentation intended by the representor to be relied upon but the representee; (2) if the misrepresentation is of such nature that it would be likely to play a part in the decision of a reasonable person to enter into a transaction it will be presumed

> that it did so unless the representor satisfies the court to the contrary ... (3) the misrepresentation does not have to be the sole inducement for the representee to be able to rely on it : it is enough if the misrepresentation plays a real and substantial part, albeit not a decisive part ... (4) the presumption of inducement [may be] rebutted…"

257. Accordingly on its own case Medpro's case on reliance, which is fundamental to its case on all its true estoppel arguments, finally hinges on establishing material representations which are apt to engage the presumption of inducement – see Arden LJ's mention of "*such nature that it would be likely to play a part in the decision of a reasonable person"* .

258. This therefore comes back to the absence of clear representations. But in addition the presumption of inducement cannot be deployed where reliance would not be reasonable. Here Medpro is essentially saying that its failure to comprehend what were the requirements for the multi-million pound contract which it sought to win should not lie at its door, because it relied on statements made by its counterparty (which conflicted with the contractual terms to which both parties signed up). As Mr Stanley KC noted in argument, there is a considerable oddity in a commercial case where the supplier of specialist goods says that it relied upon representations by the purchaser that the offer complied with technical standards. It follows that it would not be reasonable for Medpro to rely on DHSC's statements or actions during due diligence as "trumping" the contractual terms.

259. It is also a point to note that the presumption of inducement is one generally seen in the context of representations and is not, conventionally, applied to estoppel by convention/acquiescence.

Estoppel and validated process/SAL

260. While Medpro maintained in closing that the estoppel case extended to validated process to the extent that the validated process argument crosses over with SAL, no estoppel can arise. This is essentially for the same reason outlined above as to Medpro's case on construction: that it was agreed that the compliance with SAL was satisfied by provision in advance of the partial certification, and photos of gowns with an NB number which was not apt to sterile gowns. Medpro says *"Ultimately, it was for the DHSC, through the Technical team, to determine whether the documents provided by PPEM met the necessary technical requirements, and before the gowns were purchased."*

261. There plainly is no representation which can be spelled out of the circumstances here, as to validated process and SAL – particularly when the complications of the process form part of the backdrop: how could it be understood that DHSC were satisfied that gowns would be sterile if they were as presented? At this level Medpro's case becomes that DHSC agreed or represented or the parties assumed that the kind of non-sterile gowns which were not needed could be the sterile gowns which were needed.

262. The estoppel case could therefore only conceivably work if SAL were independent of validated process. Then there might be room for a

representation/assumption that all that was needed (in terms of validation of process) to demonstrate compliance with SAL was compliance with ISO 11137. However that case itself would fail for the same reasons as the ETS arguments already considered. There is no clear representation (again see the relevant backdrop of what the process is covering), there is no evidence of assumption, there is no evidence of reliance, and there is no presumption of inducement.

Non-Reliance and Entire Understanding Clauses

263. Finally there is the Non-Reliance clause and the Entire Understanding clause, which can be dealt with relatively briefly.

264. Clause 28.5 of the Contract's Schedule 2 (General Terms and Conditions) agreed that neither party has relied on any statement that is not *"set out in this Contract or ... made fraudulently"*. Under Clause 28.5 the parties further agreed not to claim damages for any such (non-contractual, non-fraudulent) *"misrepresentation or undertaking (whether made carelessly or not.)"*. This is, the kind of clause which not infrequently underpins a case in contractual estoppel (ie deployed against claims of reliance on extra contractual misrepresentations). Medpro's attempts to suggest that this clause was not apt to cover more than claims for damages for misrepresentation or breach of warranty appears to ignore the opening words of the clause which are not so limited *("Each party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract…"*).

265. The Entire Understanding clause, clause 28.9 appears, like the clause in *ABN Amro Bank NV v Royal & Sun Alliance Insurance* [2021] EWCA Civ 1789, [2022] 1 WLR 1773 to exclude estoppels.

266. Accordingly had the estoppel case been capable of getting off the ground on its merits, it would then have faced insuperable difficulties in the contractual terms, this being a case where fraud is not suggested as a way round the relevant clauses.

REMEDIES

The Issues

267. There are essentially three questions which arise at this stage.

    a. Did DHSC validly reject the gowns? If it did, DHSC says that by one route or another it is entitled to recover the price it paid, and no question of assessing loss (or mitigation) arises;

    b. If DHSC did not validly reject the gowns, so that it is entitled only to damages for loss, what is that loss? At that point it becomes necessary to consider issues of mitigation and whether the gowns, although not contractually compliant, had a value to DHSC for which allowance should be made;

c. In either case, what additional loss is DHSC entitled to recover? In that respect, DHSC claims in relation to the costs of storing and disposing of the gowns;

Was the right to reject lost?

268. As already described:

a. It is common ground that delivery (being ex works) took place when the gowns were made available for collection at the gates of the sterilisation facilities in China;

b. DHSC rejected the gowns on 23 December 2020;

c. The rejection letter sent by DHSC made reference only to the fact that the gowns' packaging and boxing did not bear a CE marking with a NB number. It did not, in particular, raise the point as to validated process.

269. Medpro contends that:

a. DHSC is not, on the facts, entitled to avail itself of any purported rights under clause 4.2 of Sch. 2 because there was no visual inspection *"within a reasonable time following delivery (or such other period as may be set out in the Key Provisions, if any)"*;

b. Clause 6.1 of Sch. 1 (Key Provisions) stipulated a 21-day period from delivery within which there had to be a visual inspection by DHSC;

c. There was no such visual inspection. The first lot was available for collection from 12-15 July 2020, correlating with 21 days expiring in early August 2020;

d. Accordingly, there was no entitlement for DHSC to reject under clause 4.2 of Sch. 2.

270. DHSC did not join issue on this point. It relies rather on clause 4.6 of the Contract. That provides:

> "Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 4.7 of this Schedule 2, if at any time following the date of delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("Defective Goods"), the Supplier shall, at the Authority's discretion:
>
> 4.6.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by repairing such Defective Goods; or

> 4.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 4.2 to 4.5 of this Schedule 2."

Pursuant to cl. 4.8, that right to reject had to be exercised *"within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Key Provisions, if any".* DHSC also relies on the common law and Sch. 2, cl. 7.3, which gives a right of rejection in the event of breach of cl. 7.2 (which required valid CE marking).

271. Medpro contends that DHSC lost the right to avail itself any purported rights of timely inspection and rejection under clause 4.6 of Sch. 2, because of the portion of clause 4.8 of Sch. 2 which stated that the clause 4.6 *"rights and remedies ... shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods ....."* Medpro says that it is obvious that DHSC *"might reasonably be expected to discover"* that the boxes carried a CE mark and no NB number and that accordingly, DHSC cannot rely on the "first inspections" carried out *"on or around 11 September 2020*".

272. DHSC's argument is not on its face attractive, but requires to be carefully considered because of the highly unusual factual circumstances – and the rather recherche nature of the breaches. DHSC says that the reality is that Covid made it practically impossible to carry out meaningful investigations in China, where the goods were already packed and sealed in containers at the sterilisation plants, and from which they were then transferred (in sealed containers) for shipping. It also obviously put enormous pressure on those inspecting goods and clarifying apparent gaps in documentation, who had to give priority to the most urgently needed goods (which the gowns were not). DHSC therefore says that the first real opportunity for any inspection therefore occurred when the goods arrived at Daventry, which was the "delivery address" specified in the Order Form. The first goods arrived there at some point in late August, and they were inspected (through photographs) by Ms Naeem of the MHRA on 11 September 2020.

273. Ms Naeem first queried the compliance of the goods following her (remote) inspection on 11 September 2020. At that point, the DHSC knew that the CE marking of the gowns was apparently defective (in that it did not bear any notified body number), but it claims that it would not have been apparent whether this was simply a formal error (e.g. the inadvertent omission of the notified body number in printing) or something more important. Nothing was at that point known about failure to comply with BS EN 556-1:2001, or the actual sterility of the gowns.

274. After that DHSC points out that between 22 October 2020 and November 2020 there were communications between the parties (and the MHRA) about the gowns and what would be done in relation to them. It is evident from the communications that Mr Page and Mr Ellis of 4C Associates (for DHSC) spoke over the phone. Medpro did not challenge Ms Naeem's evidence on the steps she took, and the time she took, to inspect the goods and for an incident to be raised by the MHRA, and it did not cross-examine Mr Taylor at all.

275. Overall DHSC's submission was that, bearing in mind (a) the circumstances under which it, the MHRA, and Medpro were working because of Covid, (b) the need to understand why the gowns were not validly CE-marked and what information was actually available to attest their sterility, (c) the need to explore whether there were ways, short of rejection, to resolve those issues, it cannot be said that more than a reasonable time had passed since discovery of the defect. Moreover, on 23 December 2020, DHSC still knew only of the CE marking breach. It follows that rejection was permissible under Schedule 2, clause 4.6.

276. One point which DHSC skated over throughout was the position of Uniserve. Up until the start of trial it had been in issue whether Uniserve was DHSC's agent. That was reluctantly conceded; and in closing it was said that *"even assuming Uniserve to have been an agent in a relevant sense"* DHSC could not have discovered any breaches (though CE marking alone might be arguable – it being contended that even for that it was necessary to seek documents from Medpro and to inquire into the nature of the defect).

277. The reason for this coyness as regards Uniserve was the consequence of an admission that Uniserve was the agent of DHSC – as it plainly was. The contract was an ex works contract. DHSC retained Uniserve to act for it. It is not right to say that no useful inspection could be performed by Uniserve on delivery. Obviously Uniserve could not conduct empirical tests for sterility; but as made clear above it was inherent in the nature of the goods and the terms of the contract that no-one would ever expect that to be done. The better and significant question is: could Uniserve inspect for CE marking? Again no-one would expect each item to be inspected; but it is tolerably clear that individually wrapped and CE marked gowns would be expected to be packed in boxes with CE marking. Uniserve plainly could inspect for that and indeed could open a box and check a few wrapped gowns visually. There was no reason why such inspection had to wait until the goods arrived in the UK. And indeed Ms Naeem's initial inspection was never designed to do more than Uniserve could have done – and in the circumstances (they live on the ground and she being necessarily inspecting remotely via photos) it was less thorough than anything Uniserve could have done. Against that background was the rejection for failure to CE mark within a reasonable time? The answer is self evident: no it was not.

278. Does that mean that there was an existing right to reject for the other breaches? I consider that there was not, essentially for similar reasons to those which drive the conclusions on the CE marking. In essence validated process is the proxy for sterility in the sense of SAL, and in the absence of an agreed alternative means of giving the assurance of the SAL, CE marking is the outwards and visible sign of the validated process which is the proxy for SAL. The three breaches in this case stand or fall together at this stage, as they were established together at the earlier stage. This also forms the reason why the DHSC's argument that more time should be allowed to enable it to determine if the inadequate CE marking was a "formal error" is misconceived (and contrary to DHSC's arguments at an earlier stage). There has been no evidence to explain how there could be such a thing; indeed the backbone of the "validated process" argument was that there could be no such thing.

279. It need not have been so, of course. Had the Contract stipulated for a genuine "*equivalent technical solution*" to the default means of having a validated process for the requisite SAL it is possible that it would have been one which could not sensibly have been deputed to Uniserve; though an ex works contract where compliance could not be judged until after international transport would be a little surprising. The likelihood however is that such a process would have equated to the presentation of each batch with a portfolio of certificates speaking to the relevant stages, and that could have been checked. However this is a counterfactual which does not arise in this case.

280. It therefore follows that DHSC lost the right to reject when it did not perform an inspection and communicate rejection within a reasonable time.

281. This effectively dictates the answer so far as any statutory right to reject is concerned: whether as a matter of contract or common law, rejection must occur within a reasonable time. That reasonable time must take into account time of delivery, contract terms and so forth. Thus the same answer would result.

Damages: The value of the Gowns and Mitigation

282. If there was no valid rejection DHSC is entitled to damages or an indemnity. The question is: how much? DHSC says it is the entire value of the Contract, as the gowns could not be used and therefore had no value. Medpro contends that this is a considerable oversimplification.

283. It is common ground that:

    a. The *prima facie* measure of loss is *"the difference between the value of the goods at the time of delivery to the buyer and the value they would have had if they had fulfilled the warranty."* (Sales of Goods Act 1979, s 53(3));

    b. Clause 10.4 of Schedule 2 of the Contract, put DHSC under a positive obligation ("shall") to *"at all times take all reasonable steps to minimise and mitigate any loss for which [DHSC] is entitled to bring a claim"*.

284. There was therefore a freestanding duty which sat alongside the Common Law rules. However it was not suggested by either party that this made a difference in real terms to the analysis.

285. The real issue is whether the gowns had a nil value because the gowns were unusable in the NHS or any other setting. The first stage of this issue concerns their potential use as sterile gowns.

286. This can be dealt with relatively swiftly. DHSC contracted for sterile gowns, but received gowns that were not (contractually speaking) sterile, or properly validated as being sterile, and not properly CE marked. That means that they could not be used as sterile gowns in the NHS or elsewhere. Mr Horkan, DHSC's only (official) factual witness on this topic was working as Clinical Procurement Lead – Product Assurance & Quality Control for DHSC at the material time. His evidence was categorical; his team would not have considered using the gowns as sterile surgical gowns. There is no evidence to suggest that they could be used

as sterile gowns elsewhere – this is not, for example, a case where the gowns did not comply with UK regulations, but did comply with (say) the regulations in place for sterile gowns in Australia.

287. The question which follows and which Medpro asks is this: Even if the gowns could not be used as sterile gowns, why could they not have been repurposed for use in the NHS as non-sterile/isolation gowns, or sold elsewhere for use as non-sterile/isolation gowns? This is the kernel of Medpro's case on failure to mitigate. Its pleaded case was that: *"Any alleged lack of sterility and/or valid CE markings …did not prevent the said gowns from being used within the NHS or from being sold to third parties outside of the EU."*

288. The real question was about what use or sales could have been made. It was not in issue that there was no evidence that (if there was a use to be made or a sale to be had) DHSC had taken reasonable steps to avail itself of it. As Medpro pointed out, Mr Horkan's evidence was that he had not been involved in any discussions about minimising or mitigating any losses following DHSC's decision not to use the gowns, he had no evidence to give more broadly in relation to any steps taken to do so, and he was not aware of any discussions about the potential useability of the gowns outside of the NHS.

289. Before entering into the evidence it is essential to identify what legal principles this argument engages. The "duty to mitigate" is a concept often lightly alluded to. The following points must be borne in mind:

    a. There is no such thing as a "duty to mitigate" as a separate concept: *"[It] is now well recognised that mitigation is not a duty owed to the wrongdoer but is an aspect of causation: … The principle is that if the claimant chooses to respond to the defendant's breach of duty in a way that would not reasonably be expected, damages will be assessed as if the claimant had responded in the expected way, even though in fact it did not."* (Lord Leggatt in *URS Corporation Ltd v BDW Trading Ltd* [2025] UKSC 21 (21 May 2025) at [175]);

    b. The point arises as part of the exercise of proving causation when the Defendant denies causation. Once the point has been raised the onus of proof is on the defendant *"who must show that the claimant ought, as a reasonable [person], to have taken certain steps to mitigate [their] loss and that the claimant could thereby have avoided some part of his loss";*

    c. Where there is an available market, the claimant is expected to enter the market to obtain a substitute: [176];

    d. More generally what is reasonable for a person to do in mitigation of their loss is one of fact in the circumstances of each individual case: Bankes LJ in *Payzu Ltd v Saunders* [1919] 2 KB 581, 588;

    e. While the innocent party is not under an obligation to do anything other than in the ordinary course of business (see *British Westinghouse Electric and Manufacturing Co Ltd v Underground Electric Railways* [1912] AC 673 at 689) and it is not obliged to take risks with its own money (see *Jewelowski v*

Propp [1944] KB 510), the claimant may have to take an obvious step even if is not part of its ordinary business: *LSREF III Wight Ltd v Gately LLP* [2016] EWCA Civ 359.

290. There are then two elements to the mitigation case advanced by Medpro. The first is that the gowns could have been used in the NHS or elsewhere in the UK as isolation gowns. The second is that the gowns could have been sold internationally (again as isolation gowns).

291. Turning to the evidence, there are problems. This is not a case where there was a market in the sense often found in sale of goods cases. That being the case, the court is reliant on the specific factual and expert evidence called by the parties. Medpro called no factual evidence and DHSC's factual evidence, as outlined above, did not really progress matters.

292. As for experts, it is fair to say that neither side called evidence which truly fitted with the expert issues. These were as follows:

> "in the field of the supply and procurement, use and valuation of medical equipment on the following issues:
>
> (i) whether the gowns supplied to the Claimant, even if they or a proportion of them, did not have a SAL of 10 -6, might nonetheless have been repurposed or used in the NHS; and
>
> (ii) any market(s) in which they could have been sold and their value in such market(s)."

293. DHSC called Mr New. Mr New was the CEO of SCCL, a provider of some of DHSC's factual witnesses, and a body at the heart of the NHS supply chain which, at the relevant time was owned and operated by DHSC. As such Mr New was really closer to a factual witness than an expert. And to the extent he had expertise it was in relation to NHS usage – he frankly admitted to having no knowledge or expertise in markets for sale of unwanted NHS items (specifically gowns).

294. Mr Popovic for Medpro had previously worked in a procurement function for the NHS. While I have no doubt that he was doing his best to assist the court – and his report evidenced substantial and detailed work and appended many exhibits - it was apparent from his report and CV that his previous experience in the NHS is in relation to pricing services internally and that his expertise is in valuation. He had no experience in the supply and procurement of medical equipment or (more specifically) medical devices; nor did he have any expertise in relation to selling NHS goods abroad or in the regulatory hurdles which might apply in other jurisdictions.

295. The evidence base for this issue therefore is not particularly robust and must be carefully considered.

296. Medpro's first suggestion was that there was a failure to mitigate because *"at the very least"* DHSC should have made enquiries about the re-labelling and/or re-packaging of the gowns so that they could be deployed in the NHS. This however was only really (even hypothetically) an option if the goods were sterile, such that

they could properly be re-labelled or re-packaged. However, given the conclusions already reached this does not arise.

297. The second suggestion was (as noted) deployment in the NHS as isolation gowns. However as the factual background has already disclosed, one thing the NHS did not need at this point was more isolation gowns. That timeline evidence was echoed by Mr New's evidence that by December 2020 as a result of "panic buying" it had already obtained 500 weeks'/nearly 10 years' worth of gowns. While there was some attempt to say that things might not have been quite so bad if DHSC had acted promptly, there was no real challenge to the NHS oversupply argument. One suggestion which is likely to occur to anyone who lived through Covid in this jurisdiction is whether sales could have been made to domestic private buyers. However this was not Medpro's case; Mr Popovic did not identify any potential domestic private buyers. In the absence of a formal market, of course, to do so other than by a process of random enquiries might well have been difficult. But the result was that the instinctive thought that they might have gone into (say) the broader care sector was not an argument in play.

298. It was therefore really the third possibility which came most sharply into focus. Mr Popovic's report suggested that international demand was demonstrated by reference to: (i) the "*rapid ramp up"* in Chinese exports, as seen in the GACC data; (ii) the comparable jump in UK and European import data showing highly elevated import levels, that, shortly thereafter, track closely the Chinese export data when visualised in graphic form; (iii) the fact that, well into 2021, various countries were still experiencing shortages of PPE; and (iv) reflecting this, the fact that export levels, even many months after the initial spike in export data, remained extremely high, at 250% of pre-pandemic levels.

299. In a sense however this highlights the problem with Mr Popovic's evidence. Although manifestly doing his best, it falls some way short of setting out one or more examples of "certain steps" which DHSC could have taken which would have mitigated loss. It is true as Medpro submitted that Mr Popvic's research indicated a "*large degree of loosening"* of regulatory requirements across jurisdictions in response to the pandemic emergency, and it was a legitimate view by reference to his analysis of the data that there was a seller's market for gowns *"for most of the period up until November 2021"*. A sellers' market however does not correlate to evidence that there was an available market – and Mr Popovic accepted that there was no single global market on which gowns could have been placed. Nor does a sellers' market mean that jurisdiction A or jurisdiction B was actually in the market for gowns at this time – or that the DHSC sellers could access the market.

300. Mr Popovic's evidence focussed on three jurisdictions: Australia, Canada and Brazil. None of these were the types of "*low and middle income*" jurisdictions in relation to which he had identified, on the basis of the evidence, shortages at this point in time. As regards these jurisdictions:

    a. Australia: Mr Popovic focussed on an exemption for contracts approved by the relevant authority and a derogation for goods which met other international standards;

b. Canada: Mr Popovic's evidence was that "As the Gowns were compliant with the EN 13795 series, and if evidence of sterility could have been provided, they could have been potentially placed on the Canadian market as sterile gowns, or alternatively repackaged and relabelled and placed on the market as non-sterile gowns.". Accordingly on the facts of this case, Canada would only accept these gowns as non-sterile gowns;

c. Brazil: the suggestion was that there was a procedure for importation of goods that met a foreign standard.

301. Accordingly it is fair to say that his evidence (i) went no further than the availability of those jurisdictions depending on local authorities deciding that the gowns could have been admitted to those markets, and compliance with standards which Mr Popovic did not identify and on which he would have been unable to comment (ii) did not engage with whether there was a shortage of non-sterile gowns in those jurisdictions at the relevant time. Further his evidence that developed nations had excess inventories of PPE by late 2020, leading to a fall in prices, suggests that there was no need in these jurisdictions.

302. As for other possibly relevant jurisdictions Mr Popovic again gave helpful evidence on the existence of similar derogations and relaxations of rules geared towards sterility, but did not identify any jurisdictions where (i) derogations would permit these gowns (with their particular peculiarities) to be classed as sterile (ii) non sterile gowns were in short supply at this time. Overall in fact his evidence did serve to highlight the complexities involved. Absent a global market, what DHSC would need to do is to identify either (i) (based on a consideration of the relevant regulatory regimes and exceptional derogations/relaxations) jurisdictions where the gowns would be accepted as sterile or (ii) jurisdictions where non-sterile gowns were sought.

303. As to the former point the absence of this work within Mr Popovic's own report, and the complexities of the regulations considered in argument, speak together – that was not a realistic option. As to the latter Mr Popovic suggested during cross-examination, based on his experience as Director of Pricing Delivery and Development at NHS Improvement, that it would be reasonable to expect that the relevant individual(s) within the NHS or DHSC, *"would have […] contacts across the globe to [their] opposite numbers"* to explore what selling opportunities might be available. That was however based on an expectation derived from his own work in a different field, and therefore essentially speculative. Mr New, while himself not the right person to give evidence as to foreign sales relationships, was closer to the relevant position, and his evidence was that SCCL did not have access to buyers outside of the NHS (or some external organisations in respect of NHS work). That was credible evidence, when placed against the known facts as to the nature of the NHS and what it does. The NHS is not in general terms a seller of goods, but a consumer of them.

304. Further the evidence as to the requirements of a procurement process both illustrated why there probably was no such contact, and the difficulties which could be expected if (somehow) a relevant contact had been made.

305. The first of these concerns relabelling. It appeared to be Mr Popovic's evidence (reflected in his valuations) that even if the gowns were destined for use as non-sterile gowns they would need to be relabelled. While one might think that isolation gowns would not need relabelling, that was not the case he advanced. And since the label was inside the package relabelling would also require repackaging.

306. As for the second aspect, not only would relabelling have a significant cost, Mr New explained how relabelling would require a procurement process taking 9-12 months and considerable management time. Although the evidence was not entirely specific on this, one then has to consider the logistics of a sale. It was not the case that those involved could simply ping an email to their (hypothetical) opposite numbers offering to sell the gowns. Such an approach would fall foul of exactly the same rules which would require a procurement process externally. At this end, the DHSC would require a reverse procurement exercise to establish that goods were not being sold off in a *quasi* private deal which would carry obvious corruption risks. It also seems likely that in most potential buyer jurisdictions a correlate inwards procurement process would have been required.

307. Essentially, having failed to reject the goods effectively, and without an open market into which the goods could be sold with greater ease (and then relabelled and on sold by a more commercially agile entity), DHSC found itself between a rock and a hard place. Thus, while the absence of any efforts to sell the gowns is on its face highly unattractive, Medpro have had an opportunity to critique what was done. Careful thought has been put into advancing a case as to how DHSC fell short and that case has been tested at trial. That exercise has demonstrated that there was no realistic identifiable route to selling or deploying these gowns. DHSC's failure to act was not one which led to the loss of an opportunity to reduce the financial damage. The case on failure to mitigate fails. Consequently DHSC is entitled to recover the cost of the gowns.

Damages: The Claim for Storage Costs and Gown Disposal

308. DHSC has also claimed the costs which it says it incurred in having to store and dispose of the gowns that it could not use or sell. The claim for cost of disposal was abandoned, but the storage claim (£8,648,691) remained. It was advanced on the basis of a spreadsheet, entitled the Storage Costs Spreadsheet. The document was introduced by a sole witness, Mr Johnathan Bates. From October 2020 Mr Bates was the head of PPE analysis and data at the DHSC.

309. There is no issue that contractually storage costs would be recoverable. That is clear from Schedule 2 clauses 4.3, 4.5 and 7.3. There would also be no reason why such costs could not be recovered as damages.

310. Nor was there really an issue with the calculation within the spreadsheet. That was clearly explained by Mr Sampson and effectively agreed by Mr Cukier.

311. The issue here was proof of the quantum: the combination of the lack of underpinning of the spreadsheet, combined with Mr Bates' own lack of personal knowledge of the spreadsheet. As the relevant section leader, he was sent to court to verify and defend a document produced by others within his group, who it was

not considered fair to expose to cross examination. While this was a kind and worthy approach, it was not, in probative terms, helpful.

312. The net result was that this claim rested on a spreadsheet of which Mr Bates was not the author and he had no direct involvement in its creation or development as a living document. He had first discussed it only a week before giving his evidence, for the purpose of ensuring he understood it well enough to give evidence on it. While in broad terms he had direct knowledge of the underlying data sources used to compile it, it did not seem (and would not have been likely) that he had seen, considered or grappled with the underlying data. He had not, for example, seen the underlying stock model data that was a key basis for the spreadsheet. He had no information as to where the costs in the spreadsheet had come from and had not inspected any storage cost invoices.

313. Ultimately while it was Mr Bates' evidence that the figures presented should err on the side of caution *("we have deliberately built in underestimates throughout this is inevitably at a low side estimate of the costs. Every single decision point where we could take A or B, we have taken the route that gives us the lowest cost."*) the net result was that the Court was effectively being asked to take on trust the figures set out in the spreadsheet. While not in any way denigrating the diligence or the abilities of those who compiled and worked on the spreadsheet, that is simply not an adequate way of advancing a claim for over £8 million.

314. That is the more so when the claim is not entirely vanilla. A simple example can be given. Here the way the claim was advanced was by reference to the overall costs of storage – the underlying invoices were for storage costs in general – they were not specific to the Medpro items because that was not the way in which billings to DHSC were done. It was not possible to interrogate the invoices themselves because, although disclosed documents, they were not included in the bundles for trial (DHSC having resisted their inclusion). There were other points which might profitably have been explored with a witness who had handled the raw data: an example was the approach to gap filling and "smoothing" of data (one tab of the spreadsheet related to "smoothed data") where underlying documents were massing or anomalous.

315. Mr Sampson, to whom the unattractive task of presenting this portion of the case fell, did the very best that he could with the materials available. He may be right that even if the spreadsheet's author had been the witness, and the witness statement had been properly supported by the underlying documents so that the quantum could be effectively audited, investigated and challenged, there would have been problems in establishing precise costs prevailing at particular points of time so as to verify or adjust parts of the claim. However, the court and Medpro were not given that opportunity. The result is that while doubtless there were storage costs which would have been recoverable, DHSC has failed to prove this element of the claim. The storage costs claim is dismissed.

THE COUNTERCLAIM

316. Originally Medpro's counterclaim ranged widely over the ground of common mistake, unilateral mistake, collateral warranty, implied terms and negligent misstatement. By the time of the hearing the case advanced had narrowed to common mistake and negligent misstatement only.

317. In some ways those counterclaims were reflections of the main case.

    a. The case in common mistake was that subjectively both parties intended that it was for the DHSC to assess and determine whether the gowns complied with the applicable legal and regulatory requirements as to CE marking, in particular in light of the relaxation of the requirements for CE marking, and that it was for the DHSC to apply for a derogation if that was necessary. It therefore contended that the Contract should be rectified accordingly;

    b. The case in negligent misstatement was that if that the gowns did not meet the relevant technical or regulatory requirements, DHSC breached its duty of care in making the statements and/or omissions which formed the basis for the earlier arguments.

Common mistake and rectification

318. It is a rare case where rectification succeeds. This is not that case.

319. For such a plea to succeed, it would be necessary for Medpro first to show at least that it (meaning the person responsible for entering into the contract on its behalf) made a mistake: see *FSHC Group Holdings Ltd v Glas* [2019] EWCA Civ 1361, [2020] Ch 365 at [105]; *Murray Holdings Ltd v Oscatello Investments Ltd* [2018] EWHC 162 (Ch) at [198]. This is not a simple matter to prove, even when an appropriate witness is called: see *Tartsinis v Navona Management Co* [2015] EWHC 57 (Comm) at [85].

320. As regards the primary construction issue (SAL) Medpro has accepted that it understood the Contract to require product with this SAL. The case as to EN 556-1 and CE marking is neither here nor there for these purposes. Rectification therefore cannot assist Medpro.

321. But even if the secondary arguments on construction were key, this argument could not succeed. Rectification is all about the parties' subjective intentions being at odds with the terms of the contract. There is – by Medpro's own deliberate choice – no evidence on this. Medpro seeks to rely on evidence given by DHSC's witnesses, but they cannot give evidence as to Medpro's subjective intentions.

Negligent misstatement

322. Medpro argued that the DHSC owed it "*a duty of care in tort properly to advise it and communicate to it what was required of it [Medpro], in relation to obtaining any applicable necessary technical and regulatory approval in respect*

of the Contract". That is, in the context of commercial parties entering into a deal worth £122 million, a bold submission.

323. It is well and long established that, in general the law does not require commercial parties entering into contracts to look out for each other, or advise: *"The law does not impose a general duty of care in the conduct of contractual negotiations, reflecting the fact that each party is entitled, within the limits set by the law, to pursue its own interests."* Lord Reed at [42] in *Cramaso LLP v Ogilvie Grant* [2014] UKSC 9, [2014] AC 1093. Of course, the particular relationship between the parties may cause a duty to advise; and if representations are made which the representor can reasonably foresee are likely to be relied on, to take care. But the basis for the duty needs to be established.

324. Medpro's submission that it was wholly reliant upon DHSC for advice is, on the facts, utterly unrealistic. Medpro was presenting itself to DHSC as a worthy entrant into the fast lane for approval as a supplier and aiming to land contracts worth hundreds of millions of pounds of public money. It said repeatedly that it had experience. It claimed to be well established: Mr Barrowman's years of experience were trumpeted, as was its track record *"manufacturing large quantities for the Australian government"* as well as Mr Page's *"We are certain that we are 100% compliant"*.

325. It is neither here nor there that Mr James did in fact try to clarify and advise to some extent. In the circumstances there is no basis for a general duty to advise.

326. The other claims under this head are grounded in the submission that the *"approved by Technical"* statement was negligently wrong. One problem here is essentially the same one that afflicts this argument in the context of estoppel: "*approved by Technical*" is not a clear representation that gowns presented exactly as per the photos would comply with the contract terms. It was in fact saying, and in the context this was its objective meaning (and was true), that the first stage (persuading DHSC that Medpro was capable of sourcing compliant products) had been passed.

327. In terms of intention for reliance, Medpro's case (that DHSC must have appreciated that Medpro would rely on this) is also fundamentally undermined by the fact that the next stage was production, negotiation, and approval of draft contracts. There is no good reason why DHSC would at the due diligence stage have thought that (the experienced and confident) Medpro would cling to a one liner in an email from someone in Opportunities, rather than reading the terms of the Contract and ensuring the contract obligations matched what it proposed to deliver.

328. This then impacts on the question of reasonable reliance (if there had been evidence of reliance, which of course there was not). If this is not a duty to advise situation it would not be reasonable for Medpro to rely on representations made in speed during negotiations, when it was the supposedly experienced provider – and had a detailed draft contract setting out requirements.

329. The claim therefore fails on multiple levels. Had the claim succeeded, the loss claimed is not the correct measure of loss, and the correct measure of loss has not been proved (or even addressed).

CONCLUSION

330. It follows from the above that:

a. Medpro was in breach of contract in that the Gowns did not comply with the requirement of (i) validated process demonstrating sterility level 10^{-6} (ii) compliance with EN 556-1 (iii) CE marking including notified body number;

b. DHSC did not effectively reject the Gowns;

c. It can nonetheless recover the full value of the Gowns as damages: the evidence as to alternative uses of these (effectively) non-sterile Gowns does not show that it was probably possible for them to be sold elsewhere to mitigate the loss;

d. However DHSC cannot recover the £8 million which it claimed for storage costs. That loss was not proved on the evidence adduced at trial;

e. Medpro has no counterclaim against DHSC either for rectification or damages.

ANNEX 1: STATISTICS, PHYSICAL TESTING AND STERILITY

331. The question here is the contingent question of whether, had a different view been taken on the question of the contractual meaning of sterility and the knock-on effects as regards the contractual obligations, DHSC has proved on the balance of probabilities that the gowns were not sterile. This encompasses the majority of the expert evidence, as it raises issues of statistics and of sterility/sterilisation of medical devices.

The testing

332. Over the course of 2022, DHSC procured sterility testing on 120 gowns from Swann-Morton (Microbiological Laboratory Services) Limited ("Swann-Morton") and 20 of the gowns from Synergy Health Ireland trading as Steris Laboratory Tullamore ("Steris").

333. The Swann-Morton testing was carried out in two tranches of 60 gowns (30 being tested aerobically and 30 being tested anaerobically), with gowns of each size being tested:

    a. The first tranche of 60 gowns was tested between April and June 2022. 26 out of 30 gowns failed the aerobic test; 29 out of 30 gowns failed the anaerobic test;

    b. The second tranche of 60 gowns was tested between August and October 2022. 26 out of 30 gowns failed the aerobic test; 22 out of 30 gowns failed the anaerobic test.

334. Between November and December 2022, Steris also carried out (less detailed) microbiological identification. Of those 20 gowns, 19 were found to be not sterile.

Statistics

335. From the DHSC's perspective the answer here was straightforward. 103 out of 140 gowns tested failed the sterility tests. It says that the testing done was sufficient to establish on a balance of probabilities that the gowns did not meet the required SAL of 10^{-6}. The specified SAL of 10^{-6} permits no more than 25 out of 25 million gowns to fail a sterility test. Professor Hutton points out that the minimum failure rates demonstrated by the testing are already well above the failure rate tolerated by the required SAL. For example, of the 3.75m small gowns, the SAL of 10^{-6} would require that no more than 4 fail, yet the observed number of failed gowns is hugely in excess of that figure. The number of failures is said to be so high that it does away with any challenge by Medpro on the selection of the samples in that even if DHSC had selected only those gowns that were not sterile in the entire population and sent those to Swann Morton for testing, the required SAL of 10^{-6} has not been met.

336. This gave rise to a very interesting debate about the nature of a sample for statistical purposes and whether any inference could be drawn from a non-representative and non-random sample. This was an area in which it emerged that expert input might well have been useful in the formulation of the questions for

the experts, as well as the answers, with DHSC's eminent (and on her own subject extremely impressive) expert witness Professor Jane Hutton, stating that the question should have been "*given the results that we have got, what are the possible explanations of evaluative opinion?"* – or to posit that in the terms of this case: what statistically valid conclusions can be drawn from the results of the Swann-Morton testing?

337. In fact the evidence on sampling seemed only to underscore the reasons why this was not an appropriate way of testing for sterility. Unless one were prepared to descend into the byways of statistical evidence there would be no way of robustly testing unless one could establish a "representative" sample; and in a population of gowns of this nature unless one had some way of knowing what strata were likely to be of interest—and there are many possible candidates—no stratified sampling method could easily be devised. In addition, the evidence as to the nature of the sterility definition meant that extrapolating from actual samples was conceptually entirely at odds with the nature of the exercise.

338. As to what one might nonetheless gather from the evidence and the statistics, the statistical arguments cannot determine the matter. While, regardless of the debate on the optimum method of sampling (on which it seemed clear that the method used was not remotely the optimum method: in that the Swann Morton testing which formed the original basis for the case involved only 2 out of about 540 containers over 14 storage sites, and related to the work of only one of the sterilisation facilities) I might have been inclined to see force in the submission that as a matter of probability 55 non-sterile gowns in a population of 25 million means that there was probably a breach of the sterility requirement, that "analysis" proceeds on the basis that the samples as tested were representative of the samples as delivered. That creates a real problem given that there was no evidence of this – a topic to which I return further below.

339.

The evidence and its implications

340. There is nonetheless a need for a view to be taken as to whether the micro-organisms fond are explicable or more likely to be explicable by reason of the contamination of the gowns after they had been sterilised. On this difficult question it is unfortunate that it cannot be said that the expert evidence on either side was of the highest quality.

341. Dr Richards, called for DHSC, did not perform particularly well as a witness. While he plainly, from his expert report, had the relevant expertise (albeit not necessarily particularly recent, with his last audit engagements being in the 1990s) he gave the impression of not having engaged particularly rigorously with the exercise he was being asked to perform. A good example was his response when asked about the Joint Report – a key document for the Court's purposes. He said *"I think you need to ask that question of your expert because he wrote the report. I was just reviewing and signing off on the report.."* This gave the impression that he had not engaged with care in signing off on a critical document and that he had not prepared carefully to give his evidence orally. Elsewhere Mr Samek mercilessly exposed examples of generalisations, loose assumptions and

failures to dig into the relevant evidence. Dr Richards also occasionally lost the train of his thoughts or did not accurately recall the questions.

342. Mr Atchia for Medpro was certainly no better. He was, despite the making of a succession of fairly major mistakes in his report (such as his misleading equation of a SAL with a log reduction in micro-organisms, or his equally misleading presentation of Dasheng's dosimetry setting)., extremely dogmatic, and unwilling to make proper concessions for example when refusing repeatedly to concede that the Dasheng exercise was not about establishing the sterilisation dose, and then having had to concede it, refusing to delete the words which were, given the concession plainly inaccurate. His evidence was on occasion plainly overstated – his description of the relevant micro-organisms as "*bilge water specialists"* is a good example, as is his trumpeting of *lactobacillus yapensis* as a *"Rosetta Stone species"* which existed only in one trench in the Pacific. There was a distinct impression that he sought to overbear both Mr Stanley and the court with a document dump of citations (numbers of which on probing proved not to exist or not to be relevant to the proposition cited) and with fluent and dogmatic answers. He left the distinct impression of a lack of neutrality.

343. It is probably sufficient to summarise the position on the evidence thus:

    a. The testing results were puzzling to the experts. Both experts would have expected different species of micro-organisms to have been recovered as adventitious bioburden on the gowns, with this adventitious bioburden being derived from various sources, for example, raw materials, the manufacturing environment, process contamination and from personnel;

    b. The isolates recovered were ones which typically would be recovered from environmental habitats;

    c. There were no expected adventitious contaminants such as skin commensals;

    d. Some environmental contaminants – but not necessarily the ones found - might be transferred in the manufacturing process;

    e. This left a question as to whether that was because there was later environmental contamination, or whether contamination with both human and environmental micro-organisms had occurred in manufacturing, with only those organisms connected with human contamination being destroyed by the irradiation;

344. There were also some puzzles deriving from the facts that:

    a. One of the contaminants *Lysinibacillus yapensis*, was a species which was not isolated until 2017, when it was recovered from the deep sea Yap Trench;

    b. another *Ornithinibacillus contaminans* is documented in a blood sample in Sweden;

    c. a third *Bacillus mojavensis* was (as its name suggests) first isolated in the Mojave desert;

d. others found in one or more of the samples (or their close relatives) have been associated with marine environments.

345. It was hard to assess what weight should be given to these facts. Although Dr Richards said that these might have occurred from a number of environmental sources, there was no detailed explanation of what that meant or where other samples of these contaminants had since been found.

346. In addition the effect of a radiation dose of 18 kGys on the particular micro-organisms was unclear. While Dr Richards accepted that some of these prima facie marine or marine associated micro-organisms might have been introduced via a shipping container which was never cleaned.

347. There were however a number of indications which provided a real case for DHSC's preferred analysis of contamination during manufacturer.

a. The first – and most significant - is that the tested gowns showed no signs of the wrappings having been soaked (cardboard) or pierced (plastic). There was no material testing of the packaging, but both experts had agreed that it was suitable for the purpose, implying that it should not be permeable, and the testing facilities noted no problems with it at the time of testing of the sample gowns.

b. While Dr Richards agreed that permeability would not necessarily be visually apparent, there were, even in theory limited ways in which permeability could happen – the expectation (agreed to by both experts) is that in the normal run of events this packaging should keep micro-organisims (and other contaminants) out.

c. The permability theories of Mr Atchia were predicated on the potentially abnormal conditions which could not be excluded from having happened. Mr Atchia posited the possibility of bacilli penetrating plastic pores but on the evidence that theory was not supported by any research. He cited two pieces of literature to support the notion that plastic may be permeable or porous to gas or water vapour—but that takes matters no further, since bacilli, while tiny, are vastly larger than gas or water molecules. He also cited one theoretical experiment that showed that bacilli could move through deliberately created small channels in a silicon chip but that does not advance matters, as he accepted. Ultimately his theory was a speculative one based on a combination of heat and pressure creating an aerosol which could permeate plastic. It was not particularly convincing, particularly given the other weaknesses in his evidence.

d. The irradiation dose seems on the evidence – see [ref**] above – not to have been sufficient that one would expect gowns with a high bioburden to be sterilised. A sterilisation dose of 18KGy would be sufficient for a bioburden per item of 13 cfu; the evidence suggests that the bioburden on these gowns may well have been higher. One cannot be sure because (i) the tests carried out by GTTC and Intertek were done as part of the manufacturing process and Dr Richards considered that they did not permit conclusions about bioburden, and (ii) the calculation used is one designed to establish bioburden for dose

setting. However if that approach is robust (which is logical, if not supported by the experts – Dr Richards not having grappled with it and Mr Atchia predictably fighting the suggestion) figures given in the tests carried out by GTTC and Intertek are for between 14 and 77 cfu per 100cm, the bioburden on the gowns was between 6,000 and 9,000 cfu and would have required a dose of nearly double that applied.

e. There is some evidence of sub-standard practices at the manufacturing sites. Medpro's disclosure contained inspection reports produced variously by Medpro, Eric Beare and Testcoo. These reports included photographs of the manufacturing environment in the factories which led Dr Richards to conclude that they indicated a *"poor level of compliance with established quality systems standards and Good Manufacturing Practices in terms of clothing, personnel cleanliness and environmental controls."*. Even Mr Atchia accepted that workers wearing short sleeves within the factory setting is not best practice and that that the photographs of gowns trailing on the floor, personnel wearing street shoes and operating without hair protection were not ideal. Mr Atchia attempted to dismiss the significance of these photographs as typical of such manufacturing environments because different departments would operate different levels of control, but that did not seem to deal with the evidence that there appear to have been opportunities for a high bioburden to have been acquired via the manufacturing process.

The evidence gap

348. There are therefore pieces of evidence both statistical and as to sterility which the sides pray in aid. The question is whether on that basis it would have been possible to conclude that the cause of the sterility findings ex post facto was manufacturing contamination or contamination in transit – or whether neither conclusion can be drawn and the matter must rest with the burden of proof.

349. Here the time which had elapsed and the very sketchy (to put it politely) chain of custody evidence meant that there were huge hurdles to concluding that any robust conclusions could be drawn from the Swann Morton samples. In terms of assessing the evidential picture there is a large gap whose significance cannot be ignored or (as DHSC would seek to do) treated as an irrelevance. For clarity the reasons are as follows.

350. Testing occurred more than 1 ½ years after delivery. While Medpro overstates matters somewhat in its closing, I accept that, in order to draw proper and meaningful conclusions about the state of the gowns at the point of delivery, part of the key evidential base is material which would show or enable a conclusion to be drawn on the balance of probabilities that the gowns when tested were in precisely the same condition and state as they were when delivered and that any of the contamination that was discovered on testing could not or was unlikely to have occurred by reason of anything that took place between delivery and testing;

351. DHSC had the knowledge of what happened to the gowns in the crucial intervening period between delivery and testing. The evidence served by DHSC did not come close to evidencing the journey of the gowns generally or the tested gowns in particular. DHSC had the option and ability to test on delivery. It did

not do so. It chose to test later. That being the case the evidential burden falls on it to establish there was no change of condition in the intervening period.

352. To do this the court would expect to have heard from witnesses in relation to the delivery, loading, transport, transhipment, storage and selection of the Medpro gowns, DHSC called two witnesses of fact, Mr Parkes and Mr Reid who, by their own admission, could give no relevant evidence regarding the specifics of the Medpro gowns. Mr Reid thought Mr Parkes should know about it, but he apparently did not.

353. While it might be argued that, so long as the gowns were visibly in intact packaging at the time of testing there could have been no contamination, this would be an overreach. Dr Richards' evidence was that the plastic packaging was in his opinion capable of withstanding normal conditions of use within the distribution chain for handling and routine transportation. He did not deal with the possibility of contamination from something outside routine conditions, and there was no evidence that the life journey of the gowns – taking in transportation, handling on discharge, destuffing, restuffing, further transportation and storage – was entirely within normal or routine conditions. He accepted that he proceeded on that assumption. Although one of the expert issues was the "*relevance and significance of transportation and storage conditions in relation to the sterility of the gowns supplied by [Medpro]"* he was not provided with and did not ask for material on this.

354. Both Dr Richards and Prof Hutton (in the absence of full evidence) proceeded in their analysis on the assumption that containerised goods were effectively safe from contamination. This is, of course, not a safe assumption (explosions, faulty gaskets, handling damage, rust are all possible vectors for damage to containerised cargo). While they were criticised for their assumptions by Medpro, the reality is that they were doing their best to assist the court and were not aware, outside their expertise, of the factors which might come into play. However the court cannot make those assumptions.

355. While there is no positive evidence which indicates a particular factor which would have caused contamination, there are facets of the partial picture which emerges which indicate at least some non-normal conditions. These include the length of time the gowns were in containers (at least six months- obviously less of a factor than if they were cocoa beans[3], but still an abnormality) many of them in open air conditions rather than in controlled or even covered ambient conditions; and that fact that some at least of the containers appear to have been stored in an open field for at least 3 months. That, Dr Richards agreed, was not a suitable environment.

356. Further while it may be that the positive evidence on contamination from extraordinary events was vague or speculative, that was in essence a product of the evidential vacuum created by DHSC. If the events post delivery had been known and evidenced, the parties could have determined what issues might or

[3] *JB Cocoa Sdn Bhd & Others v Maersk Line As T/A Safmafine (The "Maersk Chennai")* [2023] EWHC 2203 (Comm)

might not arise which could compromise biosecurity of the gowns and deal with the precise risks.

357. Ultimately it is simply not possible to say with any confidence that the gowns as tested were in the condition they were in on delivery.

Conclusion

358. Ultimately as indicated I am left with the following difficulties (i) large unaccounted for gaps in the gowns' history, which could have led to contamination (ii) puzzling testing results which do not point squarely to manufacturing contamination (iii) lack of positive evidence of contamination in transit. In essence a concatenation of uncertainties.

359. Had the history of the gowns' peregrinations been more clear, and had that disclosed that there was no obvious environmental cause of contamination I would – just - have formed the view that the evidence of manufacturing contamination was more probable than not.

360. As it is the other uncertainties – and in particular the lack of any proper chain of custody evidence - mean that I conclude that it is not possible to say that it is more probable than not that the contamination was caused on manufacturing. Essentially there are weak cases for both outcomes.

361. Although DHSC attempted to persuade me that the authorities (in particular the Popi M) favour a positive conclusion, I agree with Mr Samek that where there is a combination of weak evidence and massive evidential gaps (caused by a failure on the part of one party to provide relevant evidence) it is wrong to say that one should simply opt for the more probable of the two weak cases. Here one might say that there is a 40% case for DHSC, a 30% case for Medpro and an evidential gap of 30%. One cannot simply cancel out the 30% which would tell us whether (for example) there were the kinds of conditions which might engage Mr Atchia's speculative theory, or conversely show that nothing particularly risky happened.

362. Because the missing evidence is evidence legally within DHSC's control that absence must lie at its door. This is in essence a case where an adverse inference is entirely sensible and permissible on the basis of the authorities (such as *Wiszniewski v Central Manchester Health Authority* [1998] PIQR 324, 340; *Magdeev v Tsvetkov* [2020] EWHC 887 (Comm), [147]-[154] and *Efobi v Royal Mail Group* [2021] UKSC 33, [41]). On the basis of the evidence I conclude that (i) had sterility been capable of being tested for this way and (ii) had the case not already been decided on other bases I would have concluded that taking the absence of evidence and the evidence favouring in transit contamination together the claim failed, alternatively that DHSC had not discharged the burden of proof upon it.

ANNEX 2: RELEVANT PROVISIONS OF THE CONTRACT

1. The Contract between DHSC and Medpro consists of a front page and several documents:

    1.1. An order form, signed by both parties;

    1.2. Schedule 1 containing Key Provisions;

    1.3. Schedule 2 containing General Terms and Conditions;

    1.4. Schedule 3 containing Definitions and Interpretations;

    1.5. Schedule 4 containing Additional Special Conditions; and

    1.6. A set of annexures "A1" to "A9" which together were headed "technical specification".

Order Form

2. Section 5 of the Order Form "*The Supplier shall supply the deliverable described below on the terms set out in this Order Form and the Schedules and Annex A. Unless the Contract otherwise requires, capitalised expressed* [sic] *used in this Order Form have the same meanings as in Schedule 3. In the event of any conflict between this Order Form and the Schedules, this Order Form shall prevail*."

3. Section 6 of the Order Form provides for a table of goods, with columns for product description, product category, an NPC, EN#, CE#, FDA#, colour, size and total number of items, as well as unit price, total price, and currency. In the column for the EN number, it states 13795-1:2019. The columns for the CE and FDA numbers remained empty.

4. Section 7 of the Order Form is headed "Specification" and states: *"The specification of the Deliverables is as set out in Annex A.1 – A.9 [26.06.2020]. Not as embedded/attached documents. Please confirm which documents are inserted into the Annex*", underneath which is a table for the type of documents. A tick was made in the boxes for "Product tech spec", "Test certification", and "EN certification". No ticks were made in the "CE Certification", "FDA Certification" and "Photographs" boxes.

Schedule 1

5. Clause 1.1 of Schedule 1 states that "The Supplier shall supply the Goods ordered by the Authority under this Contract:

> …
>
> 1.1.5 in accordance with any quality assurance standards as set out in the Key Provisions and/or in the Order Form.
>
> …
>
> 1.1.6 in accordance with the Law and with Guidance".

6. Clause 2.2 of Schedule 1 states that the Order Form is to "*include, without limitation, the Authority's requirements in the form of its specification and other statements and requirements, the Suppliers responses, proposals and/or method statements to meet those requirements, and any clarifications of the Supplier's responses, proposals and/or method statements as included [i]n these terms and conditions*".

7. Clause 3 of Schedule 1 is headed "*Quality assurance standards*" and states: *"The following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods:* ***EN 13795-1:2019***". (Bold in the original).

8. Clause 4 of Schedule 1 states "*The Authority shall issue a Purchase Order to the Supplier in respect of any Goods to be supplied to the Authority under this Contract. The Supplier shall comply with the terms of such Purchase Order as a term of this Contract and shall ensure that the any Purchase Order is clearly noted on each delivery. For the avoidance of doubt, any actions or work undertaken by the Supplier under this Contract prior to the receipt of a Purchase Order covering the relevant Goods shall be undertaken at the Supplier's risk and expense and the Supplier shall only be entitled to invoice for Goods covered by a valid Purchase Order*".

9. Clause 5 of Schedule 1 states "*Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be deemed to be a breach incapable of remedy for the purposes of Clause 12.4 (i) of Schedule 2*".

10. Clause 5.4 of Schedule 1 states: "*The Authority shall provide the Supplier with any reasonable and proportionate cooperation necessary to enable the Supplier to comply with its obligations under this Contract. The Supplier shall at all times provide reasonable advance written notification to the Authority of any such cooperation necessary in circumstances where such cooperation will require the Authority to plan for and/or allocate specific resources in order to provide such cooperation*".

11. Clause 8 of Schedule 1 states: "*The Authority may terminate this Contract by issuing a Termination Notice to the Supplier at any time on* ***one (1) months'*** *written notice*". (Bold in the original)

12. Clause 9 of Schedule 1 states: "*Either Party may terminate this Contract by issuing a Termination Notice to the other Party if such other Party commits a material breach of this Contract in circumstances where it is served with a valid Breach Notice having already been served with at least [two (2)] previous valid Breach Notices within the last twelve (12) calendar month rolling period as a result of any previous material breaches of this Contract which are capable of remedy (whether or not the Party in breach has remedied the breach in accordance with a Remedial Proposal). The twelve (12) month rolling period is the twelve (12) months immediately preceding the date of the [third] Breach Notice*".

13. Clause 12 of Schedule 1 is headed "Supply of PPE Goods". It provides:

> "*Regulatory Requirements*
>
> 12.1 The Supplier acknowledges and understands that when procuring PPE the Authority is required to ensure the PPE Goods are compliant with and meet applicable legal and regulatory requirements.
>
> 12.2 The Supplier shall supply the PPE Goods to Authority in accordance with the terms of this Contract and in accordance with the relevant requirements of applicable laws and regulations applicable to the supply of PPE, including, as applicable, the EU PPE Regulation 2016/425, the Personal Protective Equipment (Enforcement) Regulations 2018 and the Medical Device Regulations 2002 (together the "PPE Laws").
>
> 12.3 Save in relation to any PPE Goods for which the Supplier has approval in accordance with the cross-Government Decision Making Committee and without prejudice to the generality of clause 12.2, the Supplier shall ensure for PPE Goods supplied:

12.3.1 the appropriate conformity assessment procedure(s) applicable to the PPE Goods have been followed;

12.3.2 all declarations of conformity and approvals required by PPE Laws are in place prior to the delivery of any PPE Goods to the Authority;

12.3.3 where required by PPE Laws, there is a CE mark affixed to the PPE Goods in accordance with the PPE Laws; and

12.3.4 where, necessary current EC-type examinations certificates are in place for the PPE Goods.

12.4 If there are any PPE Goods supplied to the Authority hereunder that require a CE mark under more than one set of regulations, due to the nature of those PPE Goods, including and not limited to:

- PPE Laws;
- Control of Lead at Work Regulations 2002;
- Ionising Radiations Regulations 2017;
- Control of Asbestos Regulations 2012;
- Control of Substances Hazardous to Health Regulations 2002; and
- any other relevant regulations,

the Supplier shall ensure that the CE marking for any such PPE Goods is affixed in accordance with the relevant requirements and shall indicate that the PPE Goods also fulfils the provisions of that other regulation or regulations.

Goods bought to the market before 21 April 2019

The Supplier shall provide details, including any EC-type examination certificates and approval decisions issued under Directive 89/686/EEC and Directive 93/42/EEC (if applicable), and corresponding national implementing legislation, of any PPE Goods supplied under this Contract that have been placed on the market before 21 April 2019 and products already in the distribution chain by that date confirming that these can continue to be supplied as PPE to the Authority until 21 April 2023, unless their certificate or approval will expire before that date.

Other Specific Requirements

12.6 The Supplier shall offer to the Authority spares and consumables required for any of the PPE Goods supplied to the Authority. The Supplier agrees any charging rate for the spares and consumables shall be inclusive of all packaging and standard delivery.

12.7 The Supplier shall ensure that each delivery of PPE Goods shall be properly labelled in accordance with PPE Laws and such labelling and any user instructions relating to the use of the PPE Goods is clearly legible and in English.

12.8 The Supplier shall ensure that all PPE Goods are covered by a valid EU Declaration of Conformity, translated into English and shall

> procure that this shall be retained by the Supplier and its Sub-contractors for at least 10 years following the delivery date to the Authority."

Schedule 2

14. Clause 4 of Schedule 2 sets out provisions on inspection, rejection, return and recall.

15. Clause 4.2 states: "*Without prejudice to the provisions of Clause 4.6 of this Schedule 2 and subject to Clause 4.7 of this Schedule 2, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out in the Key Provisions, if any) and may by written notice reject any Goods found to be damaged, or delivered late, or otherwise not in accordance with the requirements of this Contract ("Rejected Goods"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract*".

16. Clause 4.3 of Schedule 2 states: :

> Without prejudice to the provisions of Clause 4.5 of this Schedule 2, upon the rejection of any Goods in accordance with Clauses 4.2 Schedule 2, the Supplier shall at the Authority's written request:
>
> 4.3.1 collect the Rejected Goods at the Supplier's risk and expense within ten (10) Business Days of issue of written notice from the Authority rejecting the Goods and reimburse the Authority for any Charges paid in connection with the Goods (including without limitation any pre-payment or advance payments) along with any costs reasonably incurred by the Authority as a result of any such rejection; and
>
> 4.3.2 without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority subject to the Authority not cancelling its purchase obligations in accordance with Clause 4.5 of this Schedule 2.
>
> If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated with the disposal of the Rejected Goods and the Supplier shall promptly pay any such costs".

17. Clause 4.4 states "*Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 4.3 of this Schedule 2; or (b) immediately following the expiry of ten (10) Business*

Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection".

18. Clause 4.5 states: "*Where the Authority rejects any Goods in accordance with Clauses 4.2 and/or 4.6 of this Schedule 2 and the Authority no longer requires replacement Goods, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid (in whole or in part) for such Rejected Goods the Supplier shall refund such payment along with any costs reasonably incurred by the Authority as a result of any such rejection to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods*".

19. Clause 4.6 states: "*Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 4.7 of this Schedule 2, if at any time following the date of the delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("Defective Goods"), the Supplier shall, at the Authority's discretion: 4.6.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by repairing such Defective Goods; or 4.6.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 4.2 to 4.5 of this Schedule 2*".

20. Clause 4.8 states: "*The Authority's rights and remedies under Clause 4.6 of this Schedule 2 shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Key Provisions, if any. For the avoidance of doubt, Goods not used before their expiry date shall in no event be considered Defective Goods following the date of expiry*

provided that at the point such Goods were delivered to the Authority they met any shelf life requirements set out in the Order Form".

21. Clause 7 of Schedule 2 sets out the warranties. Clause 7.1 provides that:

> "The Supplier warrants and undertakes that: …
>
> 7.1.1 the Goods shall be suitable for the purposes and/or treatments as referred to in the Order Form, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;
>
> …
>
> 7.1.16 where any act of the Supplier requires the notification to and/or approval by any regulatory or other competent body in accordance with any Law and Guidance, the Supplier shall comply fully with such notification and/or approval requirements;
>
> …
>
> 7.1.19 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods".

22. Clause 7.2 of Schedule 2 states:

> "Where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Goods under this Contract relates to medical devices and/or medicinal products (both as defined under any relevant Law and Guidance), the Supplier warrants and undertakes that it will comply with any such Law and Guidance relating to such activities in relation to such medical devices and/or medicinal products. In particular, but without limitation, the Supplier warrants that:
>
> 7.2.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid CE marking as required by Law and Guidance (or be subject to a Product Authorisation, as such term is defined in Schedule 4) and that all relevant marking, authorisation, registration, approval and documentation requirements as required under Law and Guidance relating to the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of such Goods shall have been complied with. Without limitation to the foregoing provisions of Clause 7.1 and 7.2 of this Schedule 2, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking, and evidence of any other authorisations, registrations, approvals or documentation required; …"

23. Clause 7.3 of Schedule 2 states: "*If the Supplier is in breach of Clause 7.2 of this Schedule 2, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier*

shall, subject to Clause 10.2 of this Schedule 2, indemnify and keep the Authority indemnified against, any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach".

24. Clause 7.6 of Schedule 2 states: "*The Supplier warrants and undertakes to the Authority that it shall comply with any eProcurement Guidance as it may apply to the Supplier and shall carry out all reasonable acts required of the Supplier to enable the Authority to comply with such eProcurement Guidance*".

25. Clause 20.1 Schedule 2, "*Subject to any statutory requirement and Clause 20.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract". Clause 20.2 adds that: "Where any records could be relevant to a claim for personal injury such records shall be kept secure and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract*".

26. Clause 23.4 states that

> "Where the Supplier enters into a Sub-contract in respect of any of its obligations under this Contract relating to the manufacture, supply, delivery or installation of or training in relation to the Goods, the Supplier shall include provisions in each such Sub-contract, unless otherwise agreed with the Authority in writing, which:
>
> 23.4.1 contain at least equivalent obligations as set out in this Contract in relation to such manufacture, supply, delivery or installation of or training in relation to the Goods to the extent relevant to such Sub-contracting".

27. Clause 28 includes:

> "28.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.
>
> 28.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.
>
> 28.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in

relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.

28.7 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 28.8 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest".

28.9 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud. Any tender conditions and/or disclaimers set out in the Authority's procurement documentation leading to the award of this Contract shall form part of this Contract."

Other Provisions

28. Section 1 of Schedule 3 provides for definitions.

""Guidance" means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, NHS Improvement, the Medicines and Healthcare Products Regulatory Agency, the Health & Safety Executive, the Office for Product Safety & Standards, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;

"Law" means any applicable legal requirements including, without limitation: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in

> England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument);
> (c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972;
> (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;
> (e) requirements set by any regulatory body as applicable in England and Wales;
> (f) any relevant code of practice as applicable in England and Wales; and
> (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);
>
> "PPE" shall mean personal protective equipment as defined in the EU PPE Regulation 2016/425".

29. A "Product Authorisation" is defined in Schedule 4, Clause 1 (applying to "Specific approval processes for medical devices that are not CE marked") as "*an authorisation from the Secretary of State for Health and Social Care pursuant to Regulation… 12(5) MDR* [for medical devices] *to be placed on the market in the United Kingdom and supplied to the Authority for use in a healthcare environment ("Product Authorisation")*" (Clause 1.1). The provisions of Clause 1 apply, inter alia, to general medical devices to which CE marking is not currently applied pursuant to Regulation 10 of the Medical Devices Regulations 2002.

30. Schedule 4 provides in Clause 1.4 that "*It is a condition of this Contract that the Supplier shall not commence the manufacture and/or the supply of Goods for use generally by patients until the Supplier has: 1.4.1 obtained a relevant Product Authorisation and notified the Authority of the same; and 1.4.2 communicated its approval of the Pre-Production Samples to the Authority in writing (such approval not to be unreasonably withheld or delayed)*".