Judiciary of England and Wales

Department of Health and Social Care v PPE Medpro Limited: Press Summary

Important note for press and public:

This summary forms no part of the court's decision. It is provided to assist the press and the public to understand what the court decided. The full judgment of the Court is the only authoritative document. Judgments are public documents and are available at: www.judiciary.uk, https://caselaw.nationalarchives.gov.uk

Neutral Citation Number: [2025] EWHC 2486 (Comm)

Background and Context

The case arose out of a contractual dispute between the Department of Health and Social Care (DHSC) and PPE Medpro Limited (Medpro) regarding the supply of sterile surgical gowns during the COVID-19 pandemic.

In mid-2020, during the COVID-19 pandemic, DHSC sought to procure sterile surgical gowns for NHS use amid ongoing supply challenges. Medpro offered to supply these gowns.

Medpro agreed to sell 25 million sterile gowns to DHSC for £122 million. After they arrived in the UK DHSC formed the view that they were not compliant with the contract. It claimed to be entitled to reject the gowns and claim the price back, as well as to claim £8 million for storage of them.

The case addresses issues of contract construction, sterility and sterility assurance, medical device regulations, estoppel, rejection and damages.

Contractual claim

The contract was a complex document which included (i) an order form which made no overt reference to recognised sterility and process validation standards and (ii) in the fuller terms detailed provisions on sterility standards, quality assurance standards, regulatory compliance, and inspection rights. [139] [179-181][Appendix 2]

The contract did (on both parties' cases) require the gowns to meet something known as a Sterility Assurance Level (SAL) of 10^{-6}. That meant (in broad terms) that the gowns had to be sterilised in such a way that no more than one in a million gowns should be non-sterile. [183]

The usual way of proving compliance with such a requirement is through a validated sterilisation process, typically aligned with standards such as ISO 11137 and EN 556-1. In the EU and UK the applicable standards and regulations required CE marking with a notified body number for sterile medical devices. [8-26]

Medpro accepted the SAL requirement but disputed the existence in this case of an independent contractual obligation to demonstrate a validated sterilisation process. The contract incorporated a document called the Essential Technical Requirements Document (ETRD) and Medpro argued that this and the Order Form (plus representations made in the pre-contractual phase) meant that the documents which it had supplied in advance of the contract constituted sufficient evidence of compliance, even though the requirements of the usual standards were not met. [50-56]

Specifically, the gowns were sterilised using electron beam irradiation at several facilities, with certifications including ISO 11137 Part 1 but lacking full validation of sterilisation dose setting as required by ISO 11137 Part 2 and EN 556-1. The gowns bore CE marks without the required notified body numbers for sterile products. [141-142]

The Court found that Medpro's case was not compatible with the requirements of SAL. On Medpro's case the parties agreed in advance that documents which were not compatible with the contractual SAL nonetheless conclusively established that the requirements of SAL were satisfied. That construction was not consistent with the contractual documents relied on by Medpro and it made no commercial sense. It was also inconsistent with other terms in the contractual documentation. [186-201]

The Court found that a SAL was usually established by proof of manufacture and sterilisation by an appropriate validated method, which comprises several steps and that that was what this contract, properly understood, required. [200-204]

Contrary to Medpro's case therefore there was a requirement to demonstrate a validated sterilisation process.

That requirement was not complied with by Medpro. Specifically it never produced anything to show that the complicated process of radiation dose setting by reference to test of the bioburden on sample gowns, irradiation and testing the results, had been done. It followed that Medpro had breached the Contract. [205-219]

The Court also found two other breaches:

(i) Failure to comply with EN-556-1 (the relevant sterility standard). This standard required a validated process and SAL 10^{-6}. The failure to show a validated process establishing the SAL meant that this requirement was breached. [224]

(ii) Failure to comply with CE marking: the provisions relied upon by Medpro were insufficient to outweigh the other provisions which on their face required CE marking. [230]

Estoppel

Medpro claimed that if it was wrong about what the contract said, DHSC was "estopped" from relying on the relevant terms. It relied on concepts of estoppel by representation or convention or acquiescence, asserting that DHSC's approval of submitted documents constituted a representation or consensus that the gowns met contractual requirements, preventing DHSC from later asserting non-compliance. [232-235]

The court rejected these arguments. It found that there was no clear representation, or assumptions. There was no consensus that Medpro could prove compliance by an "equivalent technical solution"; for one thing, the solution it relied on was not equivalent, because it did not show sterility.[239-250]

The court also found that there was no proven reliance by Medpro (which had called no evidence) and that in the circumstances (where there was no clear representation and reliance would not be reasonable) reliance could not be presumed. [251-259]

It would if necessary also have upheld contractual clauses precluding reliance on representations outside the contract unless fraudulent. [263-266]

Rejection

DHSC issued a rejection notice in December 2020. Medpro argued that DHSC lost the right to reject due to delays and that the rejection was not timely under contract clauses governing inspection and rejection.

The court found that DHSC did not effectively reject the gowns. It had an agent which could have inspected the gowns in China and so the rejection, some time after the gowns arrived in the UK did not occur within a reasonable time. [268-281]

Damages and Mitigation

DHSC sought damages capped at £128 million, including the contract value and storage costs of unusable gowns. Medpro disputed the quantum and argued DHSC failed to mitigate losses by not exploring alternative uses or sales of the gowns. Although the DHSC did not show evidence of attempts to dispose of the gowns elsewhere, the court held it was entitled to the price of the gowns as damages. This was because (i) the gowns could not be used as sterile gowns (ii) the alternative was to use them as non-sterile (isolation) gowns, however the NHS had no need for such gowns and the evidence showed no reasonable market for the gowns outside the NHS due to regulatory and procurement constraints. [282-307]

The claim for storage costs failed because of the inadequacy of DHSC's evidence. IT relied on a spreadsheet largely unsupported by underlying documents, and spoken to by a witness who had no real knowledge of the underlying material or how the spreadsheet had been put together. [308-315]

Counterclaim

Medpro's counterclaim failed. There was no common mistake between the parties. The argument that DHSC should have advised Medpro as to how to comply with the contract was contrary to long established legal principle. [316-329]

Conclusion

The court concluded:

- 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;
- DHSC did not effectively reject the gowns;

- 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;
- However DHSC cannot recover the £8 million which it claimed for storage costs. That loss was not proved on the evidence adduced at trial;
- Medpro has no counterclaim against DHSC either for rectification or damages.