[redacted]

Dear [redacted] and Ms Andrews,

Thank you for notification of the Regulation 28 Report to Prevent Future Deaths concerning the investigation into the death of June Liddell. The coroner's concerns relating to the LivaNova S5 heart lung machine were noted and an MHRA investigation was commenced to evaluate these concerns.

During the investigation, all available evidence was considered, the issues were discussed at length with the manufacturer, independent expert opinions were sought from clinical perfusionists to support next actions, and the matter was presented multiple times at multidisciplinary MHRA signal meetings where actions were agreed.

With reference to the coroner's concerns, our investigation concluded that:

- the "Arterial clamp is defective" error message concurrently shown on the separate CP5 System Panel screen to adequately indicate the issue;
- inclusion in the instructions for use (IFU) of an explanation of the "Arterial clamp is defective" message and relevant follow up action for the user would be information that could provide improved user support;
- and the existing IFU has appropriate precautionary warnings to prevent liquid ingress damage and wear and tear.

Following extensive correspondence with the manufacturer, our recommendation was to update the IFU to include an explanation of the "Arterial clamp is defective" message, along with relevant follow up action for the user. LivaNova have confirmed that the revised IFUs have been distributed to UK customers, including a customer letter, which has been published on LivaNova's website (see "Resources").

I hope this explains MHRA's position and actions taken. Please do not hesitate to contact me if you have any questions.

Kind regards,

[redacted]
Benefit Risk Evaluation Assessor
Safety and Surveillance Group

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU