



FOI 3225

Date 19/09/2024

Dear Requester,

Thank you for your Freedom of Information request. Please note, this is a cross-site response for Bedford site and Luton site.

You asked:

1) Variously known as decontamination units, CSSDs, HSDUs, SDUs, SSDs, SSDUs, SPDs, and/or SPU, does your Trust have an in-house sterile services facility / department?

If no, please indicate this (return e-mail acceptable), and thank you for your time. No further answers are required.

If yes, please support with the following:

Yes

2) What instrument tracking system does the sterile service use?

Healthedge HESSDA

3) What accreditation, if any, does the facility hold?

ISO 13485 and UK MDR accreditation

4) Does the facility process / resupply single "supplementary items or devices" to customers/clinical users?

Yes

5) If the facility supports/handles/supplies supplementary items, how is it defining them?

Usually single instruments (or small sets of instruments) not associated with an instrument set

6) Looking at the following options, which of the following methods are used by sterile services for the individual tracking and traceability of supplementary / single surgical instruments?

- **1D / traditional barcode on a traceability tag, supplied with the instrument, and returned by the clinical user**

Yes, for some supplementary items

- **2D / QR-style barcode on a traceability tag, supplied with the instrument, and returned by the clinical user**



N/A

- **Coloured instrument tape applied to the device to indicate the owner / destination**

N/A

- **KeyDot or similar system which sticks a QR-like code on to the device**

Yes, for some supplementary items

- **Laser Marking of the device, with a 2D/ QR-style code**

N/A

- **Laser Marking of the device, with a 1D / traditional barcode**

N/A

- **Laser Marking with a name, number or other human-readable text**

N/A

- **Other (please specify)**

N/A

7) Does the instrument tracking system fully-integrate with their chosen single-instrument tracking approach, or does it require third-party software, hardware or other systems to function?

Yes, tracking system does not require other systems

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If you are not satisfied with the Trust review under the Freedom of Information Act 2000 you may apply directly to the Information Commissioners Officer (ICO) for a review of your appeal decision.



The ICO can be contacted at: ICO, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF
www.ico.org.uk

Yours sincerely,

FOI Officer

Bedfordshire Hospitals NHS Foundation Trust