

Request under Freedom of Information Act 2000

Thank you for your request for information which we received on Friday 2nd August 2024. I am pleased to confirm the following.

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?

Yes

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:

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

Health Edge

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

ISO 13485/ENISO13485 (inst and flex endoscopes) & part 2 of the MDR 2002, Annex 5 & MDR 2002 Regulation 14

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?

As a supplementary item

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

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

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

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

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

Laser Marking of the device, with a 1D / traditional barcode
Laser Marking with a name, number or other human-readable text
Other (please specify)

B and D

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?

Fully supported.

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If you need any further assistance, please do not hesitate to contact us at the address above.

Yours sincerely
Freedom of Information Co-ordinator
For and on behalf of Milton Keynes Hospital NHS Foundation Trust

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