



Certificate GB21/969096

The management system of

**GBUK Group Ltd: GBUK LTD. Trading As GBUK Healthcare
And GBUK Banana GBUK Enteral Ltd. Trading As GBUK
Enteral UK Intervene Group Ltd. Trading As GBUK Intervene**

Blackwood Hall Business Park North Duffield Selby North Yorkshire YO8 5DD United Kingdom

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 30 April 2024 until 30 April 2027 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 12 March 2018

Authorised by

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Certificate GB21/969096, continued

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**ISO 13485:2016
EN ISO 13485:2016**

Issue 4

Design, develop, transfer, supply management, manufacture, import, store, export, distribute and sale of:

- Sterile and non-sterile suction systems.
- Drainage systems.
- Women's healthcare devices.
- Intravenous cannulae systems.
- Enteral products.
- PH analysis products .
- Neuraxial products.
- Blood pressure cuffs.
- Thoracic and airway management systems.
- Tubing and connectors for use in medical devices.
- Sterile bifurcated vaccination needle.
- Non-sterile fixation devices and wound care Dressings.

Design, develop, transfer, supply management, manufacture, import, store, export, distribute, sale and service of:

- Enteral syringe drivers.
- Patient moving and handling products and kits.

Manufacture, supply management, import, store, export, distribute and sale of:

- Sterile theatre procedure packs (gastrostomy).
- Colostrum collectors.



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**ISO 13485:2016
EN ISO 13485:2016**

Issue 4

Import, store, export, distribute and sale of:

- Hypodermic needles and syringes.
- The measurement and delivery of insulin.
- Infusion pumps and accessories.
- Infusion catheters.
- Urine collection products.
- Disposable medical containers.
- Urinary catheters.
- Peripheral nerve stimulators.
- Urodynamic manometric catheters.
- Urodynamic measurement systems.
- Endoscopic camera adaptors/covers.
- Wearable percutaneous catheter/tube holder
- General-body orifice lubricant sterile.
- Absorbent underpads
- Oxygen therapy products.
- Sterile ureteral stents and sets.
- Urology products.
- Sterile medical apparel and manufacture of non-sterile medical apparel.



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**ISO 13485:2016
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Issue 4

- Faecal collection systems.
- IV products and systems.
- Patient temperature management devices.
- Surgical retractors & stays and blood collection devices including lancets.
- Negative pressure wound therapy devices and dressings.
- Sterile and non-sterile fixation devices and wound care dressings (with or without chlorhexidine).



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