



Certificate GB21/969096

The management system of

**GBUK Group Ltd:
GBUK Ltd. trading as
GBUK Healthcare and Banana
GBUK Enteral Ltd. trading as Enteral UK,
Intervene Group Ltd. trading as Intervene**

Blackwood Hall Business Park, North Duffield,
Selby, North Yorkshire, YO8 5DD, UK

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 14 December 2021 until 11 January 2025
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.

Issue 2. Certified since 12 March 2018



Authorised by



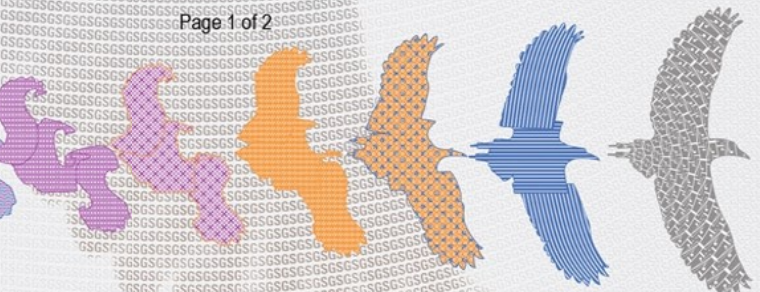
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21HC:13485:2016:0421:M2

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

Issue 2

Detailed scope

- Design, manufacture, distribution, storage and sales of sterile and non-sterile suction systems, drainage systems, women's healthcare devices, intravenous cannula systems, enteral products, neuraxial products, blood pressure cuffs and thoracic and airway management systems.**
- Service of enteral syringe drivers**
- Distribution of devices for the measurement and delivery of insulin**
- Distribution of hypodermic needles and syringes**
- Design, manufacture, distribution, and service of patient moving and handling products and kits.**
- Storage and distribution of oxygen therapy products, sterile ureteral stents and sets, urology products, sterile medical apparel and manufacture of non sterile medical apparel.**
- Manufacture of procedure packs for enteral procedures, colostrum collection and ommaya reservoir procedures. Storage and distribution of faecal collection, IV products and systems, patient warming devices, surgical retractors & stays and blood collection devices including lancets.**
- Distribution, storage and sales of Negative Pressure Wound therapy Devices and dressings**
- Contract manufacture, distribution, storage and sales of tubing and connectors for use in medical devices**



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