

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

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4.)

For the following products

The scope of registration appears on page 2 of this certificate

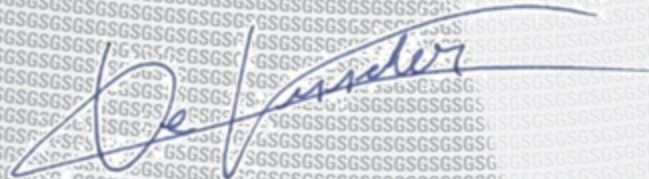
This certificate is valid from 24 March 2021 until 11 January 2024

And remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 23 April 2009.

Certification is based on reports numbered GB/PC 229743

Authorised by



Global Medical Devices Head of Notified Body

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LPMD5007 - Certificate CE1639 Annex II-4 - EN rev. 02

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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

**Therapeutic pessaries used to treat pelvic organ prolapse.
Sterile Yankauer suction handle.
Sterile and non-sterile extension sets for enteral feeding.
Sterile and non-sterile stoma EN-Plug.
Sterile enteral feeding tubes.
Sterile oral and enteral feeding syringe system.
Sterile bifurcated vaccination needle.
Sterile and non-sterile spinal syringe system (without needle).
This includes sterile and non sterile medical filters and catheter connectors.
Non-sterile introducer needle to guide the insertion and placement
of a spinal/epidural needle
Sterile wound drainage systems.
Sterile Suction Catheters (open and closed) for removal of mucus
within the respiratory tract
Enteral syringe driver for volume controlled enteral fluid delivery**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.