EC Certificate Full Quality Assurance System: Certificate GB19/963733

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 21 February 2020 until 11 January 2024
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 23 April 2009
and first certified by SGS Belgium NV since 23 August 2019.

Certification is based on reports numbered GB/PC 229743

Authorised by

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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

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.