EC Certificate Full Quality Assurance System: Certificate GB19/963733



The management system of

## **GBUK Group Ltd.**

also trading as GBUK Ltd., GBUK Healthcare, GBUK Enteral Ltd., GBUK Banana, Enteral UK Ltd., Intervene Group Ltd.

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 23/08/2019 until 11/01/2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 23/04/2009 and first certified by SGS Belgium on 23/08/2019

Re certification audit due before 24/08/2021.

Certification is based on reports numbered GB/PC 229743

Authorised by

Pieter Weterings Certification Manager

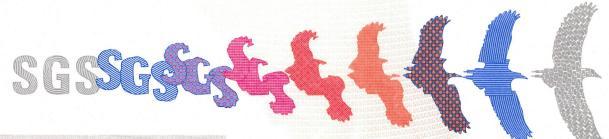
SGS Belgium NV, Notified Body 1639

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

Issue 1

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. 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