EC Certificate Production Quality Assurance System: Certificate GB19/963732



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 V
Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions

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 18/05/2012 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

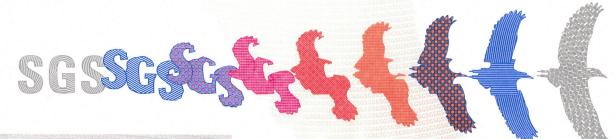
SGS Belgium NV, Notified Body 1639

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Issue 1

Detailed scope

Sterile loss of resistance syringe.

Sterile stopcock (with and without extension line).

Sterile drainage bags.

Sterile Y-Port for enteral connections.

Sterile drawing up devices (straws and needles, with and without filters).

Sterile Theatre Procedure Packs in accordance with the requirements of Directive 93/42/EEC Article 12.