



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 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 12 March 2021 until 11 January 2024  
and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 18 May 2012

Certification is based on reports numbered GB/PC/ 229743

Authorised by

Global Medical Devices Certification Manager

**SGS Belgium NV, Notified Body 1639**

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**Directive 93/42/EEC**

**on medical devices, Annex V  
Restricted to the aspects of manufacture concerned with securing and  
maintaining sterile conditions.**

Issue 6

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 chest drainage device**
- Sterile Theatre Procedure Packs in accordance with  
the requirements of Directive 93/42/EEC Article 12.**

**Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type  
Examination Certificate according to Annex III is a mandatory requirement for each device in  
Addition to this certificate to place the device on the market.**