

Declaration of Conformity		
Technical file	Enteral Drawing up Devices	
Document Reference	DOC-150	
Issue	4.0	Page 1 of 2



Declaration of Conformity

Legal Manufacturer	<p>GBUK Group Ltd GBUK Ltd. trading as GBUK Healthcare and Banana</p> <p>GBUK Enteral Ltd. trading as Enteral UK</p> <p>Intervene Group Ltd. trading as Intervene</p> <p>Woodland House Blackwood Hall Business Park North Duffield, Selby North Yorkshire YO8 5DD United Kingdom</p>
General Product Name	Enteral Drawing up Devices
Product Variants	See attached Appendix
Compliance Statement	We hereby declare that the above mentioned devices comply with the legislation of the United Kingdom transposing European Medical Devices Directive 93/42/EEC
Classification Rule	Rule 1, Annex IX, for Class I Sterile Devices
Assessment Route	Annex V for Class I Sterile Devices
Certificate Number (Issue)	Annex V Certificate: GB19/963732 (Issue 3)
Notified Body	<p>SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium</p> <p>Notified Body Number: 1639</p>

Declaration of Conformity		
Technical file	Enteral Drawing up Devices	
Document Reference	DOC-150	
Issue	4.0	Page 2 of 2

Signed:

Name: Dr Stephen Curran

Position: Regulatory Affairs Manager

Date: 19 March 2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturers name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix

Product Catalogue Number	Product Description	Classification
Enteral Drawing up Devices (Without Filter)		
119490	D-3nteral - ENFit Drawing up Straw 100mm sterile	I Sterile
119489	D-3nteral - ENFit Drawing up Straw 150mm sterile	I Sterile