

<b>Declaration of Conformity</b>		
<b>Technical file</b>	Enteral / Oral Syringe System	
<b>Document Reference</b>	DOC-E-002-NUTRICIA-SYRINGES	
<b>Issue</b>	3.0	Page 1 of 3



## Declaration of Conformity

<b>Legal Manufacturer</b>	<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>
<b>General Product Name</b>	Enteral / Oral Syringes
<b>Product Variants</b>	See attached Appendix
<b>Compliance Statement</b>	We hereby declare that the above mentioned devices comply with the legislation of the United Kingdom transposing European Medical Devices Directive 93/42/EEC
<b>Classification Rule</b>	Rule 2, Annex IX, for Class IIa and Class I Sterile & Measuring Devices
<b>Assessment Route</b>	Annex II for Class IIa Devices Annex V for Class I Sterile & Measuring Devices
<b>Certificate Number (Issue)</b>	Annex II Certificate: GB19/963733 (Issue 4)

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<b>Notified Body</b>	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium  Notified Body Number: 1639
<b>EU Authorized Representative</b>	QualRep Services BV Utrechtseweg 310 B-42 6800 AR Arnhem The Netherlands

Signed:

Position: Regulatory Affairs Manager

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.

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## Appendix

<b>Product Catalogue Number</b>	<b>Product Description</b>	<b>Classification</b>
105969	D-3nteral 10ml reusable ENFit syringe	Ila
105968	D-3nteral 20ml reusable ENFit syringe	Ila
123584	D-3nteral 60ml reusable ENFit syringe	Ila
116327	D-3nteral 1ml Low Dose Single Use ENFit Syringe	I Sterile & Measuring
121824	D-3nteral 5ml Low Dose Single Use ENFit Syringe	Ila
91421	D-3nteral 10ml Single Use ENFit Syringe	Ila
116326	D-3nteral 2.5ml Low Dose Single Use ENFit Syringe	I Sterile & Measuring
91422	D-3nteral 20ml Single Use ENFit Syringe	Ila
124823	D-3nteral 60ml Single Use ENFit Syringe	Ila
105967	D-3nteral 100ml Single Use ENFit Syringe	I Sterile & Measuring
164068	ENFIT ISOSAF 3ml Single Use ENFit Syringe	I Sterile & Measuring
164062	ENFIT ISOSAF 10ml Single Use ENFit Syringe	Ila
164061	ENFIT ISOSAF 100ml Single Use ENFit Syringe	I Sterile & Measuring
13021017	ISOSAF 1ml Low Dose Home 2 ENFit Syringe	I Sterile & Measuring
13021127	ISOSAF 2.5ml Low Dose Home 2 ENFit Syringe	I Sterile & Measuring
13021055	ISOSAF 5ml Low Dose Home 2 ENFit Syringe	Ila