

<b>EU Declaration of Conformity</b>		
<b>Technical file</b>	Enteral Oral Syringe Accessories	
<b>Document Reference</b>	DOC-E-002-A	
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## Declaration of Conformity

The EU Declaration of Conformity is under the sole responsibility of the manufacturer.

The device covered by this present declaration is in conformity with Medical Device Regulation (EU) 2017/745.

<b>General Product Name</b>	Enteral Oral Syringe Accessories
<b>Brand</b>	Enteral
<b>Product Variants</b>	See Appendix I
<b>Compliance Statement</b>	We hereby declare that the devices covered in Appendix I comply with the European Medical Devices Regulation EU 2017/745
<b>Basic UDI-DI</b>	506059088E/OAccessoriesHC
<b>Medical Device Technical File and Revision</b>	TFE-002-A Revision 1.0
<b>Intended use</b>	<p>Enteral bottle adaptors are intended to be used with ISO 80369-3 ENFit enteral syringes for putting into bottles and drawing enteral feed or medication from a bottle.</p> <p>Push fit caps are intended to be connected to an Enteral or Oral Syringe, to allow the advance preparation and secure storage and transport of medication/fluids or nutritional formula within the syringe.</p> <p>Enteral screw caps are intended to be connected to an Enteral Syringe, to allow the advance preparation and secure storage and transport of medication/fluids or nutritional formula within the syringe.</p> <p>Medicine straws are intended to be used with ISO 80369-3 ENFit® Enteral syringes for the drawing up of enteral feed and medication.</p> <p>Oral bottle adaptors are intended to be used with Oral syringes for putting into bottles and drawing enteral feed or medication from a bottle.</p> <p>Stepped bottle adaptors are intended to be used with both ISO 80369-3 ENFit enteral syringes</p>

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	and oral syringes, for putting into bottles and drawing enteral feed or medication from a bottle.
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<b>Legal Manufacturer</b>	GBUK Group Ltd  GBUK Enteral Ltd is a trading subsidiary of GBUK Group Ltd. GBUK Enteral Ltd also trade as Enteral UK.
<b>Legal Manufacturer Address</b>	Woodland House Blackwood Hall Business Park North Duffield, Selby North Yorkshire YO8 5DD United Kingdom
<b>Legal Manufacturer SRN</b>	GB-MF-000002238

<b>Authorised Representative</b>	Qualrep Services B.V.
<b>Authorised Representative Address</b>	Utrechtseweg 310 B42 6812 AR Arnhem, The Netherlands
<b>Authorised Representative SRN</b>	NL-AR-000000537

<b>Classification</b>	Class I under Rule 2, Annex VIII
<b>Conformity Assessment Route</b>	Annex II and III

Signed:

*Chloe Kelly*

Name and Function: Chloe Kelly - Head of Regulatory and Quality Affairs

Date: 10<sup>th</sup> June 2021.

Signed at GBUK Group Ltd, Woodland House, Blackwood Hall Business Park, North Duffield, Selby, North Yorkshire, YO8 5DD, United Kingdom

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 1

Product Catalogue Number	Product Description	Classification
<b>Push Fit Cap</b>		
PFC-500NS	Push fit cap (BNS)	I
PFCO-20NS	Orange push fit cap bulk non-sterile	I
PFCO-50NS	Orange Push fit cap (BNS), 4000 per box	I
<b>Bottle Adaptors</b>		
BAISO1	Enteral Bottle Adapter Size 1# (12mm – 15mm) 100 units per bag	I
BAISO2	Enteral Bottle Adapter Size 2# (14mm – 16.5mm) 100 units per bag	I
BAISO3	Enteral Bottle Adapter Size 3# (17mm - 20.5mm) 100 units per bag	I
BAISO35	Enteral Bottle Adapter Size 3.5# (19mm – 23mm) 100 units per bag	I
BAISO4	Enteral Bottle Adapter Size 4# (24mm – 26mm) 100 units per bag	I
BAISO1-S	Enteral Bottle Adapter Size 1# (12mm – 15mm) 100 units per bag, singly blistered	I
BAISO2-S	Enteral Bottle Adapter Size 2# (14mm – 16.5mm) 100 units per bag, singly blistered	I
BAISO3-S	Enteral Bottle Adapter Size 3# (17mm – 20.5mm) 100 units per bag, singly blistered	I
BAISO35-S	Enteral Bottle Adapter Size 3.5# (19mm – 23mm) 100 units per bag, singly blistered	I
BAISO4-S	Enteral Bottle Adapter Size 4# (24mm – 26mm) 100 units per bag, singly blistered	I
OBA-A	Oral Bottle Adapter Size 1# (12mm – 16mm) (100 x 1 units)	I
OBA-B	Oral Bottle Adapter Size 2# (17mm-20mm) (100 x 1 units)	I
OBA-C	Oral Bottle Adapter Size 3# (21mm-23mm) (100 x 1 units)	I
OBA-D	Oral Bottle Adapter Size 4# (24mm – 28mm) (100 x 1 units)	I
BAISO0-S	10mm ENFit Bottle Adapter & Tether	I
SBAISO	Stepped bottle adaptor	I
<b>Enteral Screw Caps</b>		
ECISO-2600BNS	ENFit screw cap BNS	I