



Declaration of Conformity – EU (MDD)

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 Directive (EU) 93/42/EEC, as amended.

General Product Name	Enteral and Oral Syringes and Accessories
Brand	GBUK Enteral
Product Variants	See Appendix I
Compliance Statement	We hereby declare that the devices covered in Appendix I comply with the European Medical Device Directive EU 93/42/EEC, as amended
Basic UDI-DI	506059088E/OSyringe4J 506059088E/OSyringeActvG2
Medical Device Technical File and Revision	TFE-002 Revision 4
Intended Use	Enteral & Oral Syringes Intended to be used for delivering liquid medication, formulated enteral nutrition/feed and hydration either orally or via a feeding tube into the gastro-intestinal tract. Catheter Tip Syringe Intended to connect to compatible medical tubing to allow irrigation, delivery or aspiration of fluids, medication or gas. Caps Intended to connect an enteral or oral syringe to a bottle to allow the advance preparation and secure storage and transport of medication/fluids or nutritional formula within the syringe. Drawing Up Devices – Medicine Straws & Filter Needles Intended to be used with ISO 80369-3 ENFit Enteral syringes for the drawing up of enteral feed and medication. Bottle Adaptors Intended to be used with ISO 80369-3 ENFit Enteral syringes for putting onto bottles and drawing enteral feed or medication.
Legal Manufacturer	GBUK Group Ltd GBUK Ltd. trading as GBUK Healthcare and Banana

	GBUK Enteral Ltd. trading as Enteral UK
Legal Manufacturer Address	Woodland House Blackwood Hall Business Park North Duffield, Selby North Yorkshire YO8 5DD United Kingdom
Legal Manufacturer SRN	GB-MF-000002238

Authorised Representative	QualRep Services B.V.
Authorised Representative Address	Utrechtseweg 310 B42 6812 AR Arnhem, The Netherlands
Authorised Representative SRN	NL-AR-000000537

Notified Body Name	SGS Belgium 1639
Notified Body Address	SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerp, Belgium
CE Certificate Number	Annex II Certificate: GB19/963733 Annex V Certificate: GB19/963732

Classification	Ila, I Sterile / Measuring, I Measuring, I Sterile
Conformity Assessment Route	Annex II for Class Ila, I Sterile / Measuring Medical Devices Annex V for Class I Sterile Medical Devices

Signed:

*Chloe Kelly***Name and Function:** Chloe Kelly – Head of Regulatory Affairs**Date:** 08 Feb 2023

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.

Appendix I

Product Catalogue Number	Product Description	Classification
Enteral Syringes		
ELDISO-1	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe	I Sterile & Measuring
ELDISO-3	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe	I Sterile & Measuring
ELDISO-5	Enteral ISOSAF 5ml LDT ENFit Sterile Syringe	IIa
EISO-1	Enteral ISOSAF 1ml ENFit Sterile Syringe	I Sterile & Measuring
EISO-3	Enteral ISOSAF 3ml ENFit Sterile Syringe	I Sterile & Measuring
EISO-5	Enteral ISOSAF 5ml ENFit Sterile Syringe	IIa
EISO-10	Enteral ISOSAF 10ml ENFit Sterile Syringe	IIa
EISO-35	Enteral ISOSAF 20ml ENFit Sterile Syringe	IIa
EISO-20	Enteral ISOSAF 35ml ENFit Sterile Syringe	IIa
EISO-60	Enteral ISOSAF 60ml ENFit Sterile Syringe	IIa
EISO-100	Enteral ISOSAF 100ml ENFit Sterile Syringe	I Sterile & Measuring
ELDISO-PFC-1	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe & PFC	I Sterile & Measuring
ELDISO-PFC-3	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe & PFC	I Sterile & Measuring
ELDISO-PFC-6	Enteral ISOSAF 6ml LDT ENFit Sterile Syringe & PFC	IIa
EISO-PFC-12	Enteral ISOSAF 12ml ENFit Sterile Syringe & PFC	IIa
EISO-PFC-35	Enteral ISOSAF 20ml ENFit Sterile Syringe & PFC	IIa
EISO-PFC-20	Enteral ISOSAF 35ml ENFit Sterile Syringe & PFC	IIa
EISO-PFC-60	Enteral ISOSAF 60ml ENFit Sterile Syringe & PFC	IIa
ELDISO-1H	Enteral ISOSAF 1ml LDT ENFit HOME Sterile Syringe	I Sterile & Measuring
ELDISO-3H	Enteral ISOSAF 3ml LDT ENFit HOME Sterile Syringe	I Sterile & Measuring
ELDISO-5H	Enteral ISOSAF 5ml LDT ENFit HOME Sterile Syringe	IIa
EISO-10H	Enteral ISOSAF 10ml ENFit HOME Sterile Syringe	IIa
EISO-20H	Enteral ISOSAF 20ml ENFit HOME Sterile Syringe	IIa
EISO-60H	Enteral ISOSAF 60ml ENFit HOME Sterile Syringe	IIa
ELDISO-1H2	Enteral ISOSAF 1ml LDT ENFit HOME2 Sterile Syringe	I Sterile & Measuring
ELDISO-2.5H2	Enteral ISOSAF 2.5ml LDT ENFit HOME2 Sterile Syringe	I Sterile & Measuring
ELDISO-5H2	Enteral ISOSAF 5ml LDT ENFit HOME2 Sterile Syringe	IIa
EISO-10H2	Enteral ISOSAF 10ml ENFit HOME2 Sterile Syringe	IIa
EISO-20H2	Enteral ISOSAF 20ml ENFit HOME2 Sterile Syringe	IIa
EISO-60H2	Enteral ISOSAF 60ml ENFit HOME2 Sterile Syringe	IIa

Product Catalogue Number	Product Description	Classification
EISO-100H2	ISOSAF 100ml ENFit HOME2 ENFit Syringe	I Sterile & Measuring
SELDISO-1	Enteral ISOSAF 1ml LDT ENFit O-Ring Sterile Syringe	I Sterile & Measuring
SELDISO-3	Enteral ISOSAF 3ml LDT ENFit O-Ring Sterile Syringe	I Sterile & Measuring
SELDISO-6	Enteral ISOSAF 6ml LDT ENFit O-Ring Sterile Syringe	IIa
SEISO-12	Enteral ISOSAF 12ml ENFit O-Ring Sterile Syringe	IIa
SEISO-20	Enteral ISOSAF 20ml ENFit O-Ring Sterile Syringe	IIa
SEISO-35	Enteral ISOSAF 35ml ENFit O-Ring Sterile Syringe	IIa
SEISO-60	Enteral ISOSAF 60ml ENFit O-Ring Sterile Syringe	IIa
SELDISO-PFC-1	Enteral ISOSAF 1ml LDT ENFit O-Ring Sterile Syringe & PFC	I Sterile & Measuring
SELDISO-PFC-3	Enteral ISOSAF 3ml LDT ENFit O-Ring Sterile Syringe & PFC	I Sterile & Measuring
SELDISO-PFC-6	Enteral ISOSAF 6ml LDT ENFit O-Ring Sterile Syringe & PFC	IIa
SEISO-PFC-12	Enteral ISOSAF 12ml ENFit O-Ring Sterile Syringe & PFC	IIa
SEISO-PFC-20	Enteral ISOSAF 20ml ENFit O-Ring Sterile Syringe & PFC	IIa
SEISO-PFC-35	Enteral ISOSAF 35ml ENFit O-Ring Sterile Syringe & PFC	IIa
SEISO-PFC-60	Enteral ISOSAF 60ml ENFit O-Ring Sterile Syringe & PFC	IIa
ELDISO-1BNS-EU	Enteral ISOSAF 1ml LDT ENFit BNS Syringe	I Measuring
ELDISO-3BNS-EU	Enteral ISOSAF 3ml LDT ENFit BNS Syringe	I Measuring
EISO-5BNS-EU	Enteral ISOSAF 5ml ENFit BNS Syringe	IIa
EISO-10BNS-EU	Enteral ISOSAF 10ml ENFit BNS Syringe	IIa
EISO-20BNS-EU	Enteral ISOSAF 20ml ENFit BNS Syringe	IIa
EISO-35BNS	Enteral ISOSAF 35ml ENFit BNS Syringe	IIa
EISO-60BNS-EU	Enteral ISOSAF 60ml ENFit BNS Syringe	IIa
ABLDS-PFCO-1-EU	Enteral ISOSAF Amber 1ml LDT BNS Syringe & Orange PFC	I Measuring
ABLDS-PFCO-3-EU	Enteral ISOSAF Amber 3ml LDT BNS Syringe & Orange PFC	I Measuring
ABS-PFCO-5-EU	Enteral ISOSAF Amber 5ml BNS Syringe & Orange PFC	I Measuring
ABS-PFCO-10-EU	Enteral ISOSAF Amber 10ml BNS Syringe & Orange PFC	I Measuring
ABS-PFCO-20-EU	Enteral ISOSAF Amber 20ml BNS Syringe & Orange PFC	I Measuring
ABS-PFCO-35-EU	Enteral ISOSAF Amber 35ml BNS Syringe & Orange PFC	I Measuring
ABS-PFCO-60-EU	Enteral ISOSAF Amber 60ml BNS Syringe & Orange PFC	I Measuring
Oral Syringes		
OS-1H	Oral 1ml Sterile Syringe Single Patient Use	I Sterile & Measuring
OS-3H	Oral 3ml Sterile Syringe Single Patient Use	I Sterile & Measuring
OS-5H	Oral 5ml Sterile Syringe Single Patient Use	I Sterile & Measuring
OS-10H	Oral 10ml Sterile Syringe Single Patient Use	I Sterile & Measuring

Product Catalogue Number	Product Description	Classification
OS-20H	Oral 20ml Sterile Syringe Single Patient Use	I Sterile & Measuring
OS-1	Oral Caretip 1ml Sterile Syringe	I Sterile & Measuring
OS-2	Oral Caretip 2.5ml Sterile Syringe	I Sterile & Measuring
OS-5	Oral Caretip 5ml Sterile Syringe	I Sterile & Measuring
OS-10	Oral Caretip 10ml Sterile Syringe	I Sterile & Measuring
OS-20	Oral Caretip 20ml Sterile Syringe	I Sterile & Measuring
ABOSPFCO-1-500NS	Box of Oral Amber 1ml BNS Syringes & Orange PFC in Separate Bags	I Measuring
ABOSPFCO-3-500NS	Box of Oral Amber 1ml BNS Syringes & Orange PFC in Separate Bags	I Measuring
ABOSPFCO-5-500NS	Box of Oral Amber 5ml BNS Syringes & Orange PFC in Separate Bags	I Measuring
ABOSPFCO-10-500NS	Box of Oral Amber 10ml BNS Syringes & Orange PFC in Separate Bags	I Measuring
ABOSPFCO-20-200NS	Box of Oral Amber 20ml BNS Syringes & Orange PFC in Separate Bags	I Measuring
Catheter Tip Syringe		
CT60	60ml Sterile Catheter Tip Syringe	I Sterile & Measuring
Caps		
PFC-100	Sterile Push Fit Cap (PFC) for Oral & Enteral Syringes	I Sterile
ECISO	Sterile Enteral Syringe Cap (Male ENFit Connector)	I Sterile
ECISO-10	Sterile Enteral Syringe Cap (Male ENFit Connector) – 10 per bag	I Sterile
Bottle Adaptors		
EMBTC-50	Sterile ENFit Milk Bottle Transfer Cap	I Sterile
Enteral Drawing up Devices		
FNISO-38	Sterile Enteral ISOSAF 5µm Filter Needle 18G x 38mm	I Sterile
FNISO-50	Sterile Enteral ISOSAF 5µm Filter Needle 18G x 50mm	I Sterile
MSISO-50P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 50mm	I Sterile
MSISO-100P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 100mm	I Sterile
MSISO-150P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 150mm	I Sterile

DOCE-002 GBUK Issue 4 CK to sign

Final Audit Report

2023-02-08

Created:	2023-01-31
By:	Owen Wright (owen.wright@gbukgroup.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA-aloOAOOnF4ERc8J-ZDiPPLJ4pFBTcLd3

"DOCE-002 GBUK Issue 4 CK to sign" History

-  Document created by Owen Wright (owen.wright@gbukgroup.com)
2023-01-31 - 3:19:50 PM GMT- IP address: 89.37.68.2
-  Document emailed to Chloe Kelly (chloe.kelly@gbukgroup.com) for signature
2023-01-31 - 3:20:24 PM GMT
-  Document e-signed by Chloe Kelly (chloe.kelly@gbukgroup.com)
Signature Date: 2023-02-08 - 10:38:09 AM GMT - Time Source: server- IP address: 89.37.68.2
-  Agreement completed.
2023-02-08 - 10:38:09 AM GMT