Declaration of Conformity – EU (MDR)

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.

General Product Name	Enteral Feeding and Drainage 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 Regulation EU 2017/745
Basic UDI-DI	506059088EntFeedAcc59
Medical Device Technical File and Revision	TFE-001a Revision 5
Intended Use	Caretip: Fixation plaster to secure the placement of a tube/catheter. Clear: Fixate NG tube or similar tubing to patient The ENFit female cap is intended to provide a seal for male ENfit connectors. Enteral Drainage Bags are designed for the passive drainage of gastric fluid The UAD2ISO enteral transition adaptor is a single use medical device, provided non-sterile. The appropriate portion of the device is complaint with ISO 80369-3, allowing the connection between ISO 80369-3 compliant devices, and non-ISO 80369-3 compliant devices ISO2UAD: Intended to facilitate enteral specific connections between ISO 80369-3 compliant connectors and non-ISO 80369-3 compliant legacy enteral connectors.

Legal Manufacturer	GBUK Group Ltd GBUK Enteral Ltd is a trading subsidiary of GBUK Group Ltd. GBUK Enteral Ltd also trade 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	I
Conformity Assessment Route	Annex II for Class IIa, 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: Mar 21, 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
Fixation Plasters		
CTG-100-NS	CareTip Grip	I
CTG-50-NS	CareTip Grip	I
CG-30	Clear Grip Plasters (30 Units)	I
CG-NS	Clear Grip Plasters.	I
MCG-50	Minicleargrip	I
Drainage Bags		
DBP-250	PVC Drainage bags 250ml (Non-Sterile)	I
DBP-500	PVC Drainage bags 500ml (Non-Sterile)	I
DBP-1000	PVC Drainage bags 1000ml (Non-Sterile)	I
DBP-1500	PVC Drainage bags 1500ml (Non-Sterile)	I
DBP-2000	PVC Drainage bags 2000ml (Non-Sterile)	I
DBP-250HT	250ml PVC drainage bag with 50cm inlet tubing and hooks	I
DBP-500HT	500ml PVC drainage bag with 50cm inlet tubing and hooks	I
DBP-1000HT	1000ml PVC drainage bag with 50cm inlet tubing and hooks	I
Female Cap		
FCISO-10	Enteral Female Cap (Non-Sterile).	I
FCISO-NS	Female ENFit Cap (white) (Non-Sterile).	I
Adaptors		
ISO2UAD	Funnel to ENFit adaptor with cap	I
UAD2ISO	Universal adaptor to ENFit ISO adaptor with tether and cap	I

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