



## 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.

<b>General Product Name</b>	Neuraxial Devices
<b>Brand</b>	GBUK Healthcare
<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 Device Directive EU 93/42/EEC, as amended
<b>Basic UDI-DI</b>	50560383NeuraxialKK
<b>Medical Device Technical File and Revision</b>	TFH-004 Revision 5
<b>Intended Use</b>	<p>The DASH 6™ Introducer Needle is intended to be used with ISO 80369-6 NRFit® compliant neuraxial spinal needle for guiding the placement of the spinal needle into the epidural/subarachnoid space</p> <p>NRFit Syringes: The device is intended to be used by a trained healthcare professional.</p> <p>The DASH 6™ Blunt Drawing Up Filter Needle is intended to be used with ISO 80369-6 NRFit® neuraxial syringes for the drawing up of neuraxial medication and anaesthetic.</p>

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

<b>Classification</b>	Class IIa Class I Sterile Class I Measuring
<b>Conformity Assessment Route</b>	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 AffairsDate: *17<sup>th</sup> May 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
<b>DASH 6® Lock Syringe (NRFit)</b>		
15011010	Dash 6® NRFit Lock 1ml Syringe (Sterile)	Ila
15010010	Dash 6® NRFit Lock 1ml Syringe (BNS)	Ila
15011030	Dash 6® NRFit Lock 3ml Syringe (Sterile)	Ila
15010030	Dash 6® NRFit Lock 3ml Syringe (BNS)	Ila
15011050	Dash 6® NRFit Lock 5ml Syringe (Sterile)	Ila
15010050	Dash 6® NRFit Lock 5ml Syringe (BNS)	Ila
15011100	Dash 6® NRFit Lock 10ml Syringe (Sterile)	Ila
15010100	Dash 6® NRFit Lock 10ml Syringe (BNS)	Ila
15011200	Dash 6® NRFit Lock 20ml Syringe (Sterile)	Ila
15010200	Dash 6® NRFit Lock 20ml Syringe (BNS)	Ila
15011600	Dash 6® NRFit Lock 60ml Syringe (Sterile)	Ila
15010600	Dash 6® NRFit Lock 60ml Syringe (BNS)	Ila
<b>DASH 6® Slip Syringe (NRFit)</b>		
15021010	Dash 6® NRFit Slip 1ml Syringe (Sterile)	Ila
15020010	Dash 6® NRFit Slip 1ml Syringe (BNS)	Ila
15021030	Dash 6® NRFit Slip 3ml Syringe (Sterile)	Ila
15020030	Dash 6® NRFit Slip 3ml Syringe (BNS)	Ila
15021050	Dash 6® NRFit Slip 5ml Syringe (Sterile)	Ila
15020050	Dash 6® NRFit Slip 5ml Syringe (BNS)	Ila
15021100	Dash 6® NRFit Slip 10ml Syringe (Sterile)	Ila
15020100	Dash 6® NRFit Slip 10ml Syringe (BNS)	Ila
15021200	Dash 6® NRFit Slip 20ml Syringe (Sterile)	Ila
15020200	Dash 6® NRFit Slip 20ml Syringe (BNS)	Ila
<b>DASH 6® Accessories</b>		
15461010	DASH 6® NRFit Extension Set with clamp (10cm) (Sterile)	I Sterile
15461020	DASH 6® NRFit Extension Set with clamp (20cm) (Sterile)	I Sterile
15461125	DASH 6® NRFit Extension Set with clamp (125cm) (Sterile)	I Sterile
15241001	DASH 6® NRFit Three-Way Stopcock (Sterile)	I Sterile
15041001	DASH 6® NRFit Syringe Cap	I Sterile
15281100	DASH 6® NRFit 5µm Drawing up Filter Straw (100mm)	I Sterile
15291050	DASH 6® NRFit 5µm Blunt Drawing up Filter Needle (18G x 50mm)	I Sterile
15491050	DASH 6® NRFit Blunt Drawing up Needle (18G x 50mm)	I Sterile
15231022	DASH 6® NRFit 0.22µm Bacterial Filter	I Sterile
15311022	DASH 6® NRFit 0.22µm Epidural Flat Filter	I Sterile
15111001	DASH 6® NRFit Needle Hub Cap	I Sterile
15171001	DASH 6® NRFit Syringe to Syringe Connector	I Sterile
<b>Manometer and Extension</b>		
15140001	DASH 6 NRFit Manometer (BNS)	I Measuring
15210040	DASH 6 NRFit Manometer Extension 40cm (BNS)	I Measuring
15210020	DASH 6 NRFit Manometer Extension 20cm (BNS)	I Measuring
<b>Introducer Needle</b>		
15090002	Introducer Needle 18G 38mm (BNS)	Ila