



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	Patient Moving and Handling
Brand	GBUK Banana
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	506040574BananaM8
Medical Device Technical File and Revision	TFB-001 Revision 3
Intended Use	<p>Banana Assist: The Assist is intended to turn patients into a prone position in the same bed or from surface to surface and back again. It may also be used to turn, reposition, assist in the cleaning of patients, and moving legs out of bed.</p> <p>Lo Raiser: The Lo-Raiser is designed to support a person in moving from the floor to a seated position, or from a seated position to a standing position.</p> <p>FloJac: The device is intended to help clinicians safely lift patients from the floor.</p> <p>Clip Sling: The GBUK Banana clip sling is intended to be used to transfer patients following a risk assessment. The sling should be used in conjunction with a mechanical lifting device (either mobile or ceiling hoist) to ensure safe lifting and repositioning of a patient.</p> <p>Flo Air: These devices are intended to assist in laterally transferring patients from one surface to another.</p> <p>Seated boards: GBUK Banana Seated Boards are intended to assist in the seated transfer of a patient from one surface to another.</p>

Lateral: GBUK Banana Lateral Transfer Boards are intended to assist in the lateral transfer of patients across a gap between two surfaces

GBUK Banana Single Patient Use (SPU) Slide Sheets are intended to reduce friction and shear during the task of moving, repositioning, or turning a patient on a surface.

GBUK Banana Disposable Slide Sheets reduce friction and shear during the task of moving, repositioning, or turning a patient on a surface.

GBUK Banana Transfer Sheets are intended to assist in the transfer of patients between surfaces

The Repositioning Sling is intended to be used to hoist a patient in a supine position for transfer, in-bed repositioning or turning.

The Flo F3 kit is intended to raise patients on a surface to enable insertion or removal of patient handling device(s) and/or insertion or removal of items underneath the patient. To assist in repositioning, turning and lateral transfer.

GBUK Banana Heavy Duty Turning Devices are intended to be placed on the floor to assist a patient in turning their lower body during a seated transfer.

The Intoprone and Orbit is intended to help caregivers turn patients into prone position.
The Orbit is additionally intended to help caregivers turn patients out of prone position.

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:

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

Date:

14th Mar 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
Patient Moving and Handling		
B-Flo34	Air Transfer Device 34" wide	I
B-Flo39	Air Transfer Device 39" wide	I
B-Flo50	Air Transfer Device 50" wide	I
QP-059150-F	Lateral Transfer Board – Folding 59cm x 150cm	I
QP-059150-R	Lateral Transfer Board – Rigid 59cm x 150cm	I
QP-059180-F	Lateral Transfer Board – Folding 59cm x 180cm	I
QP-059180-R	Lateral Transfer Board – Rigid 59cm x 180cm	I
QP-074150-F	Lateral Transfer Board – Folding 74cm x 150cm	I
QP-074150-R	Lateral Transfer Board – Rigid 74cm x 150cm	I
QP-074180-F	Lateral Transfer Board – Folding 74cm x 180cm	I
QP-074180-R	Lateral Transfer Board – Rigid 74cm x 180cm	I
QP-Leila	Lateral Transfer Board – Folding 60cm x 190cm	I
Q2Board-Q2s	Q2 Seated Board 33.5cm x 77cm	I
QBB01	Original Seated Board 77cm x 35cm	I
BB-PRIME	Prime Seated Board 26cm x 62cm	I
Wypklene-D	Wipe clean Extension Handles (Double)	I
Wypklene-S	Wipe clean Extension Handles (Single)	I
QHDPT01	Heavy Duty Patient Turning Device	I
B-EGF072200P	Pack of 2 Flat Sheets	I
B-EGF100200P	Pack of 2 Flat Sheets	I
B-EGF140200P	Pack of 2 Flat Sheets	I
B-Orbit	Orbit - Into & Out of Prone	I
B-Redi100200-FT	Versal - Universal Slide Sheet	I
B-Redi100200-W	Versal - Universal Slide Sheet	I
B-VersalPlus	Versal Plus Pack - Sling and Slide Sheet	I
DGF072200	ECO Single Patient Use Flat Slide Sheet 72x200cm	I
DGF072200H	ECO Single Patient Use Flat Slide Sheet with Handles 72x200cm	I
DGF100200	ECO Single Patient Use Flat Slide Sheet 100x200cm	I
DGF100200H	ECO Single Patient Use Flat Slide Sheet with Handles 100x200cm	I
DGF140200	ECO Single Patient Use Flat Slide Sheet 140x200cm	I
DGF140200H	ECO Single Patient Use Flat Slide Sheet with Handles 140x200cm	I
DGT072072	ECO Single Patient Use Tubular Slide Sheet 72x72cm	I
DGT072120	ECO Single Patient Use Tubular Slide Sheet 72x120cm	I
DGT072150	ECO Single Patient Use Tubular Slide Sheet 72x150cm	I
DGT072200	ECO Single Patient Use Tubular Slide Sheet 72x200cm	I
DGT100100	ECO Single Patient Use Tubular Slide Sheet 100x100cm	I
DGT100150	ECO Single Patient Use Tubular Slide Sheet 100x150cm	I

Product Catalogue Number	Product Description	Classification
DGT100200	ECO Single Patient Use Tubular Slide Sheet 100x200cm	I
DGT140200	ECO Single Patient Use Tubular Slide Sheet 140x200cm	I
DGT200100	ECO Single Patient Use Tubular Slide Sheet 200x100cm	I
DGT100230	ECO Single Patient Use Tubular Slide Sheet 100x230cm	I
DGT120200	ECO Single Patient Use Tubular Slide Sheet 120x200cm	I
DGT200140	ECO Single Patient Use Tubular Slide Sheet 200x140cm	I
B-DG-Redi100200FT	ECO Single Patient Use Versal Slide Sheet 100x230cm	I
B-DGF072200P	Pack of 2 ECO Single Patient Use Flat Sheets 72x200cm	I
B-DGF100200P	Pack of 2 ECO Single Patient Use Flat Sheets 100x200cm	I
B-DGF140200P	Pack of 2 ECO Single Patient Use Flat Sheets 140x200cm	I
PATPAQ-DGF100200	PATPAQ ECO Flat Sheets, 1 Red sheet and 1 Yellow sheet - 100x200cm	I
PATPAQ-DGF100200/H	PATPAQ ECO Flat Sheets, 1 Red sheet and 1 Yellow sheet with and without handles - 100x200cm	I
PATPAQ-DGF140200/H	PATPAQ ECO Flat Sheets, 1 Red sheet and 1 Yellow sheet with and without handles - 140x200cm	I
EGF072200	Hemmed Flat Sheet no Handles	I
EGF072200H	Hemmed Flat Sheet with Handles	I
EGF090200	Hemmed Flat Sheet no Handles	I
EGF090200H	Hemmed Flat Sheet with Handles	I
EGF100200	Hemmed Flat Sheet no Handles	I
EGF140200	Hemmed Flat Sheet no Handles	I
EGF140200H	Hemmed Flat Sheet with Handles 140cm x 200cm	I
EGT072072	Hemmed Tubular Sheet 72cm x 72cm	I
EGT072120	Hemmed Tubular Sheet 72cm x 120cm	I
EGT072150	Hemmed Tubular Sheet 72cm x 150cm	I
EGT072200	Hemmed Tubular Sheet 72cm x 200cm	I
EGT100100	Hemmed Tubular Sheet 100cm x 100cm	I
EGT100120	Hemmed Tubular Sheet 100cm x 120cm	I
EGT100150	Hemmed Tubular Sheet 100cm x 150cm	I
EGT100200	Hemmed Tubular Sheet 100cm x 200cm	I
EGT140200	Hemmed Tubular Sheet 140cm x 200cm	I
IP090195PRN	IntoProne 90cm x 190cm	I
LGF070150H	Hemmed Flat Sheet with Handles 70cm x 150cm	I
LGF070200	Hemmed Flat Sheet no Handles 70cm x 200cm	I
LGF070200H	Hemmed Flat Sheet with Handles 70cm x 200cm	I
LGF100200	Hemmed Flat Sheet no Handles 100cm x 200cm	I
LGF100200H	Hemmed Flat Sheet with Handles 100cm x 200cm	I
LGF140200	Hemmed Flat Sheet no Handles 140cm x 200cm	I
LGF140200H	Hemmed Flat Sheet with Handles 140cm x 200cm	I
LGT046060	Hemmed Tubular Sheet 46cm x 60cm	I
LGT055120	Hemmed Tubular Sheet 55cm x 120cm	I
LGT072072	Hemmed Tubular Sheet 72cm x 72cm	I
LGT072120	Hemmed Tubular Sheet 72cm x 120cm	I
LGT072150	Hemmed Tubular Sheet 72cm x 150cm	I
LGT072200	Hemmed Tubular Sheet 72cm x 200cm	I

Product Catalogue Number	Product Description	Classification
LGT100120	Hemmed Tubular Sheet 100cm x 120cm	I
LGT100200	Hemmed Tubular Sheet 100cm x 200cm	I
LGT140200	Hemmed Tubular Sheet 140cm x 200cm	I
NWF085190H	Handled Transfer Sheet 85cm x 190cm	I
NWF110190H	Handled Transfer Sheet 110cm x 190cm	I
B-TS085190H	Banana Transfer Sheet with Handles 85 x 190cm	I
B-TS110190H	Banana Transfer Sheet with Handles 110 x 190cm	I
PATPAQ-EGF090200/H	PATPAQ Flat Sheets with & without Handles (Red) 90cm x 200cm	I
PATPAQ-EGF100200	PATPAQ Flat Sheets Red & Yellow no handles 100cm x 200cm	I
PATPAQ-EGF100200/H	PATPAQ Flat Sheets Red & Yellow with handles 100cm x 200cm	I
PATPAQ-EGF140200/H	PATPAQ Flat Sheets with & without Handles 140cm x 200cm	I
PATPAQ-EGT100100	PATPAQ Tubular Sheets 100cm x 100cm	I
SGF090200R	Flat Slide Sheet - Reel of 40 Sheets 90cm x 200cm	I
SGT075120R	Tubular Slide Sheet - Reel of 48 Sheets 75cm x 120cm	I
SGT120120R	Tubular Slide Sheet - Reel of 30 Sheets 120cm x 120cm	I
SGT180120R	Tubular Slide Sheet - Reel of 20 Sheets 180cm x 120cm	I
EGT100230	Hemmed Tubular Two Toned Sheet in a drawstring bag 100cm x 230cm	I
EGT120200	Hemmed Tubular Sheet in a drawstring bag 120cm x 200cm	I
QHB02-PS	Small patient specific handling belt	I
QHBO1-PS	patient specific handling belt	I
B-Neo-Versal (Non-Padded)	Neo Versal None Padded	I
B-Neo-Versal (Padded)	Neo Versal Padded	I
SGT100200R	Tubular slide sheet 100 x 200cm (red) reel of 25	I
SGT200100R	Tubular slide sheet 200 x 100cm (red) reel of 25	I
B-FloShort34	Banana Flo - Single Patient Use, 34" Short Air Transfer Device	I
B-Lo-Raiser	Lo-Raiser manual raise	I
B-FloJac39	Banana FloJac Flat Lifting Air Device - 39"	I
B-AUS-FLOJAC39	Banana FloJac Flat Lifting Air Device - 39" – AUS Variant	I
B-FLOJACBAG	Reusable bag for Banana FloJac	I
EZ-900	Patient Padded Handling Belt, 107cm x 15cm	I
EZ-910	Patient Padded Handling Belt, 130cm x 15cm	I
EGF100100	Single Patient Use Flat Slide Sheet 100x100cm	I
EGF100150	Single Patient Use Flat Slide Sheet 100x150cm	I
EGF100100H	Single Patient Use Flat Slide Sheet with Handles - 100x100cm	I
EGF100150H	Single Patient Use Flat Slide Sheet with Handles - 100x150cm	I
LGF100100	Launderable Flat Slide Sheet 100x100cm	I

Product Catalogue Number	Product Description	Classification
LGF100150	Launderable Flat Slide Sheet 100x150cm	I
LGF100100H	Launderable Flat Slide Sheet with Handles 100x100cm	I
LGF100150H	Launderable Flat Slide Sheet with Handles 100x150cm	I
LGT100100	Launderable Tubular Slide Sheet 100x100cm	I
LGT100150	Launderable Tubular Slide Sheet 100x150cm	I
EGF120200	Single Patient Use Flat Sheet 120x200cm	I
EGF100100	Single Patient Use Flat Sheet 100x100cm	I
EGF100100H	Single Patient Use Flat Sheet with Handles 100x100cm	I
EGF100150	Single Patient Use Flat Sheet 100x150cm	I
EGF100150H	Single Patient Use Flat Sheet with Handles 100x150cm	I
LGT100150	Launderable Tubular Slide Sheet 100x150cm	I
LGF100150H	Launderable Flat Slide Sheet with Handles 100x150cm	I
LGF100150	Launderable Flat Slide Sheet 100x150cm	I
LGT100100	Launderable Tubular Slide Sheet 100x100cm	I
LGF100100H	Launderable Flat Slide Sheet with Handles 100x100cm	I
LGF100100	Launderable Flat Slide Sheet 100x100cm	I
DGF100150H	ECO Flat slide sheet with Handles 100x150cm	I
DGF100150	ECO Flat slide sheet 100x150cm	I
DGF100100H	ECO Flat slide sheet with Handles 100x100cm	I
DGF100100	ECO Flat slide sheet 100x100cm	I
B-Assist	Banana Assist	I
LGF105200H	Patient Slide Sheet Flat With Handles 105cm x 200cm Launderable	I
EGF105200H	Patient Slide Sheet Flat With Handles 105cm x 200cm SPU	I
LGT090122	Patient Slide Sheet Tubular 90cm x 122cm Launderable	I
EGT090122	Patient Slide Sheet Tubular 90cm x 122cm SPU	I
LGT090200	Patient Slide Sheet Tubular 90cm x 200cm Launderable	I
EGT090200	Patient Slide Sheet Tubular 90cm x 200cm SPU	I
LGF090200	Patient Slide Sheet Flat 90cm x 200cm Launderable	I
B-SOLOSLIDE200075	Banana SoloSlide 200 x 75cm	I
B-SOLOSLIDE200100	Banana SoloSlide 200 x 100cm	I
B-EGT100200-P	Hemmed Tubular Sheet 100cm x 200cm (EGT100200) in a Patient Care Bag	I
B-Flo-F3Kit	B-Flo-F3 x4; B-Flo-F3Cover x4	I
B-Flo-F3	Single Flo F3 inflatable device	I
B-Flo-F3Cover	Single Flo F3 SPU slide sheet bag	I
Slings		
B-SSPUC-XS	Extra Small Universal SPU Clip Sling	I
B-SSPUC-S	Small Universal SPU Clip Sling	I
B-SSPUC-M	Medium Universal SPU Clip Sling	I
B-SSPUC-L	Large Universal SPU Clip Sling	I
B-SSPUC-XL	Extra Large Universal SPU Clip Sling	I
B-SSPUC-MB1	Mixed box of Clip slings – 5 medium and 5 large	I
B-SSPUC-MB2	Mixed box of clip slings – 4 medium, 4 large and 2 XL	I
B-SSPUC-MB3	Mixed box of clip slings – 2 small, 3 medium, 3 large and 2 XL	I



Product Catalogue Number	Product Description	Classification
B-SSPUL-MB1	Mixed box of loop slings – 5 medium and 5 large	I
B-SSPUL-MB2	Mixed box of loop slings – 4 medium, 4 large and 2 XL	I
B-SSPUL-MB3	Mixed box of loop slings – 2 small, 3 medium, 3 large and 2 XL	I
B-SSPUL-XS	Hoist universal loop sling XS	I
B-SSPUL-S	Hoist universal loop sling S	I
B-SSPUL-M	Hoist universal loop sling M	I
B-SSPUL-L	Hoist universal loop sling L	I
B-SSPUL-XL	Hoist universal loop sling XL	I
B-SSPUL-XXL	Hoist universal loop sling XXL	I
B-REPOSLING	Banana Repositioning Sling 230 x 155cm	I