

<b>Declaration of Conformity</b>		
<b>Technical file</b>	Patient Moving and Handling	
<b>Document Reference</b>	DOC-B-001	
<b>Issue</b>	7.0	Page 1 of 8



## Declaration of Conformity

<b>Legal Manufacturer</b>	<p>GBUK Group Ltd          GBUK Ltd. trading as          GBUK Healthcare and Banana</p> <p>GBUK Enteral Ltd. trading as          Enteral UK</p> <p>Intervene Group Ltd. trading as          Intervene</p> <p>Woodland House          Blackwood Hall Business Park          North Duffield, Selby          North Yorkshire          YO8 5DD          United Kingdom</p>
<b>General Product Name</b>	Patient Moving and Handling
<b>Product Variants</b>	See attached Appendix
<b>Compliance Statement</b>	We hereby declare that the above mentioned devices comply with the legislation of the United Kingdom transposing European Medical Devices Regulation EU 2017/745
<b>Classification Rule</b>	Rule 1, Annex VIII, for Class I Devices
<b>Assessment Route</b>	Annex II and III for Class I Devices
<b>Basic UDI-DI</b>	506040574BananaM8
<b>EU Authorized Representative</b>	<p>QualRep Services BV          Utrechtseweg 310 B-42          6800 AR Arnhem          The Netherlands</p>

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Signed:

*Chloe Kelly*

Date: 23.06.2022

Name: Chloe Kelly

Position: Head of Regulatory and Quality Affairs

Place of Issue: Address of Legal Manufacturer as stated above

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

Product Catalogue Number	Product Description	Classification
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
Q1 Board	Q1 Seated Board 26cm x 62cm	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
B-VERSAL-SPUH	Breathable Slide Sheet	I
B-VERSAL-WH	Breathable 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

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Product Catalogue Number	Product Description	Classification
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
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

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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
IPO90195PRN	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
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

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Product Catalogue Number	Product Description	Classification
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
QHBO2-PS	Small patient specific handling belt	I
QHBO1-PS	patient specific handling belt	I
B-INBEDREPO-SPU	Single Patient Use In-Bed Reposition Kit	I
B-MDSC002-02-G	Versal Sheet Clamps x 2	I
B-Neo-Versal (Non-Padded)	Neo Versal None Padded	I
B-Neo-Versal (Padded)	Neo Versal Padded	I
B-Slide Glove	Slide Sheet Glove	I
QRS01-DSL10	Roll Board Covers	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
EZ-900	Patient Padded Handling Belt, 107cm x 15cm	I
EZ-910	Patient Padded Handling Belt, 130cm x 15cm	I
B-INBEDREPO-W	In Bed repositioning system, Versal, Clamp & Adaptor	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
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

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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
<b>Slings</b>		
B-SSPUC-XS	Extra Small Universal SPU Clip Sling	I
B-SSPUC-S	Small Universal SPU Clip Sling	I

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Product Catalogue Number	Product Description	Classification
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
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