

GBUK Group Ltd

Woodland House,
Blackwood Hall Business Park,
YO8 5DD, Selby,
UK

23/10/2023

Confirmation Letter Reference: CLNB1639 GBPC 229743

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

GBUK Group Ltd

Woodland House,
Blackwood Hall Business Park,
YO8 5DD, Selby,
UK
SRN: GB-MF-000002238

EU Representative:

QualRep Services BV
Utrechtseweg 310 B42
6812 AR Arnhem
The Netherlands
SRN: NL-AR-000000537

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,


 Pp[Sean Kelly]
 Virginie SILORET
 Global Medical Device Certification Manager
 Email: Virginie.siloret@sgs.com
 Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	ID of the corresponding MDD/device	MDD Certificate Ref (s) & NB ID
Basic UDI - 506059088EntFeedGT NC06.050ISOSAF Nutricare Nasogastric Enteral Feeding Tube 6Fr 50cm NC08.050ISOSAF Nutricare Nasogastric Enteral Feeding Tube 8Fr 50cm NC06.080ISOSAF Nutricare Nasogastric Enteral Feeding Tube 6Fr 80cm NC08.080ISOSAF Nutricare Nasogastric Enteral Feeding Tube 8Fr 80cm NC08.092ISOSAF Nutricare Nasogastric Enteral Feeding Tube 8Fr 92cm NC10.092ISOSAF Nutricare Nasogastric Enteral Feeding Tube 10Fr 90cm NC12.092ISOSAF Nutricare Nasogastric Enteral Feeding Tube 12Fr 92cm NC08.120ISOSAF Nutricare Nasogastric Enteral Feeding Tube 8Fr 120cm NC06.050ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 6Fr 50cm NC08.050ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 8Fr 50cm NC06.080ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 6Fr 80cm NC08.080ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 8Fr 80cm NC08.092ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 8Fr 92cm NC10.092ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 10Fr 92cm NC12.092ISOSAF-ROW Nutricare ROW Nasogastric Enteral Feeding Tube 12Fr 92cm	Class IIb	N/A	GB19/9 63733 NB1639

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
NC14.092ISOSAF-ROW 92cm	Nutricare ROW Nasogastric Enteral Feeding Tube 14Fr			
NC16.092ISOSAF-ROW 92cm	Nutricare ROW Nasogastric Enteral Feeding Tube 16Fr			
NC06.110ISOSAF-ROW 110cm	Nutricare ROW Nasogastric Enteral Feeding Tube 6Fr			
NC08.110ISOSAF-ROW 100cm	Nutricare ROW Nasogastric Enteral Feeding Tube 8Fr			
NC10.110ISOSAF-ROW 110cm	Nutricare ROW Nasogastric Enteral Feeding Tube 10Fr			
NC12.110ISOSAF-ROW 110cm	Nutricare ROW Nasogastric Enteral Feeding Tube 12Fr			
NC14.110ISOSAF-ROW 110cm	Nutricare ROW Nasogastric Enteral Feeding Tube 14Fr			
NC08.120ISOSAF-ROW 120cm	Nutricare ROW Nasogastric Enteral Feeding Tube 8Fr			
NC12.120ISOSAF-ROW 120cm	Nutricare ROW Nasogastric Enteral Feeding Tube 12Fr			
NC14.120ISOSAF-ROW 120cm	Nutricare ROW Nasogastric Enteral Feeding Tube 14Fr			
NC16.120ISOSAF-ROW 120cm	Nutricare ROW Nasogastric Enteral Feeding Tube 16Fr			
NC14.092ISOSAF-ROW-GW 92cm	Nutricare ROW Nasogastric Enteral Feeding Tube 14Fr			
NC16.092ISOSAF-ROW-GW 92cm	Nutricare ROW Nasogastric Enteral Feeding Tube 16Fr			
YNC06.050ISOSAF 50cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 6Fr			
YNC08.050ISOSAF 50cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 8Fr			
YNC06.080ISOSAF 80cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 6Fr			
YNC08.080ISOSAF 580cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 8Fr			
YNC08.092ISOSAF 92cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 8Fr			
YNC10.092ISOSAF 92cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 10Fr			
YNC12.092ISOSAF 92cm	Nutricare Y Port Nasogastric Enteral Feeding Tube 12Fr			
YNC06.050ISOSAF-ROW 6Fr 50cm	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube			
YNC08.050ISOSAF-ROW 8Fr 50cm	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube			
YNC06.080ISOSAF-ROW 6Fr 80cm	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube			

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
YNC08.080ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 8Fr 80cm			
YNC08.092ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 8Fr 92cm			
YNC10.092ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 10Fr 92cm			
YNC12.092ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 12Fr 92cm			
YNC14.092ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 14Fr 92cm			
YNC16.092ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 16Fr 92cm			
YNC06.110ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 6Fr 110cm			
YNC08.110ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 8Fr 110cm			
YNC10.110ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 10Fr 110cm			
YNC12.110ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 12Fr 110cm			
YNC14.110ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 14Fr 110cm			
YNC08.120ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 8Fr 120cm			
YNC12.120ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 12Fr 120cm			
YNC14.120ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 14Fr 120cm			
YNC16.120ISOSAF-ROW	Nutricare Y Port ROW Nasogastric Enteral Feeding Tube 16Fr 120cm			
YNC14.092ISOSAF-ROW-GW	Nutricare Y Port ROW GW Nasogastric Enteral Feeding Tube 14Fr 92cm			
YNC16.092ISOSAF-ROW-GW	Nutricare Y Port ROW GW Nasogastric Enteral Feeding Tube 16Fr 92cm			
NCI04.050ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 4Fr 50cm			
NCI05.050ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 5Fr 50cm			
NCI06.050ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 6Fr 50cm			
NCI08.050ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 8Fr 50cm			
NCI04.075ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 4Fr 75cm			
NCI05.075ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 5Fr 75cm			
NCI06.075ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 6Fr 75cm			
NCI08.075ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 8Fr 75cm			
NCI10.075ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 10Fr 75cm			
NCI04.120ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 4Fr 120cm			
NCI08.120ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 8Fr 120cm			
NCI10.120ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 10Fr 120cm			
NCI05.125ISOSAF	Nutricare Infant Clear Nasogastric Enteral Feeding Tube 5Fr 125cm			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
NCI06.125ISOSAF Nutricare Infant Clear Nasogastric Enteral Feeding Tube 6Fr 125cm			
NCF04.40 Nutricare Flo Nasogastric Enteral Feeding Tube 4Fr 40cm			
NCF05.40 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 40cm			
NCF06.40 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 40cm			
NCF08.40 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 40cm			
NCF04.50 Nutricare Flo Nasogastric Enteral Feeding Tube 4Fr 50cm			
NCF05.50 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 50cm			
NCF06.50 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 50cm			
NCF08.50 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 50cm			
NCF05.60 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 60cm			
NCF06.60 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 60cm			
NCF08.60 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 70cm			
NCF04.75 Nutricare Flo Nasogastric Enteral Feeding Tube 4Fr 75cm			
NCF05.75 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 75cm			
NCF06.75 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 75cm			
NCF08.75 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 75cm			
NCF10.75 Nutricare Flo Nasogastric Enteral Feeding Tube 10Fr 75cm			
NCF05.90 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 90cm			
NCF06.90 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 90cm			
NCF08.90 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 90cm			
NCF10.110 Nutricare Flo Nasogastric Enteral Feeding Tube 10Fr 110cm			
NCF12.110 Nutricare Flo Nasogastric Enteral Feeding Tube 12Fr 110cm			
NCF05.125 Nutricare Flo Nasogastric Enteral Feeding Tube 5Fr 125cm			
NCF06.125 Nutricare Flo Nasogastric Enteral Feeding Tube 6Fr 125cm			
NCF08.125 Nutricare Flo Nasogastric Enteral Feeding Tube 8Fr 125cm			
NC08.140ISOSAF Nutricare Nasojejunal Enteral Feeding Tube 8Fr 140cm			
NC10.140ISOSAF Nutricare Nasojejunal Enteral Feeding Tube 10Fr 140cm			
Basic UDI - 50560383BifurcateNeedleXL			
14011001 Bifurcated Needle			
Basic UDI - 50560383PessaryVA			
G38#0 Gellhorn Pessary, 38mm, long stem, Size 0			
G38#0S Gellhorn Pessary, 38mm, short stem, size 0			
G45#1 Gellhorn Pessary, 45mm, long stem, Size 1			
G45#1S Gellhorn Pessary, 45mm, short stem, Size 1			
G51#2 Gellhorn Pessary, 51mm, long stem, Size 2			
G51#2S Gellhorn Pessary, 51mm, short stem, Size 2			
G57#3 Gellhorn Pessary, 57mm, long stem, Size 3			
G57#3S Gellhorn Pessary, 57mm, short stem, Size 3			
G64#4 Gellhorn Pessary, 64mm, long stem, Size 4			
G64#4S Gellhorn Pessary, 64mm, short stem, Size 4			
G70#5 Gellhorn Pessary, 70mm, long stem, Size 5			
G70#5S Gellhorn Pessary, 70mm, short stem, Size 5			
G76#6 Gellhorn Pessary, 76mm, long stem, Size 6			
G76#6S Gellhorn Pessary, 76mm, short stem, Size 6			
G83#7 Gellhorn Pessary, 83mm, long stem, Size 7			
G83#7S Gellhorn Pessary, 83mm, short stem, Size 7			
G89#8 Gellhorn Pessary, 89mm, long stem, Size 8			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
G89#8S Gellhorn Pessary, 89mm, short stem, Size 8 R57#2 Ring Pessary, 57mm, without support, Size 2 R57#2S Ring Pessary, 57mm, with support, Size 2 R64#3 Ring Pessary, 64mm, without support, Size 3 R64#3S Ring Pessary, 64mm, with support, Size 3 R70#4 Ring Pessary, 70mm, without support, Size 4 R70#4S Ring Pessary, 70mm, with support, Size 4 R76#5 Ring Pessary, 76mm, without support, Size 5 R76#5S Ring Pessary, 76mm, with support, Size 5 R83#6 Ring Pessary, 83mm, without support, Size 6 R83#6S Ring Pessary, 83mm, with support, Size 6			
Basic UDI - 506059088EntCareFeedNM CF01.04.050ISOSAF Carefeed® Enteral Feeding Tube 4Fr 50cm CF01.05.050ISOSAF Carefeed® Enteral Feeding Tube 5Fr 50cm CF01.06.050ISOSAF Carefeed® Enteral Feeding Tube 6Fr 50cm CF01.08.050ISOSAF Carefeed® Enteral Feeding Tube 8Fr 50cm CF01.04.075ISOSAF Carefeed® Enteral Feeding Tube 4Fr 75cm CF01.05.075ISOSAF Carefeed® Enteral Feeding Tube 5Fr 75cm CF01.06.075ISOSAF Carefeed® Enteral Feeding Tube 6Fr 75cm CF01.08.075ISOSAF Carefeed® Enteral Feeding Tube 8Fr 75cm CF01.10.075ISOSAF Carefeed® Enteral Feeding Tube 10Fr 75cm CF01.12.075ISOSAF Carefeed® Enteral Feeding Tube 12Fr 75cm CF01.08.092ISOSAF Carefeed® Enteral Feeding Tube 8Fr 92cm CF01.10.092ISOSAF Carefeed® Enteral Feeding Tube 10Fr 92cm CF01.12.092ISOSAF Carefeed® Enteral Feeding Tube 12Fr 92cm CF01.14.092ISOSAF Carefeed® Enteral Feeding Tube 14Fr 92cm ESCF.075-ISOSAF 75cm Enteral Extension Set ESCF.150-ISOSAF 150cm Enteral Extension Set BESCF.075-ISOSAF 75cm Bifurcated Enteral Extension Set BESCF.143-ISOSAF 143cm Bifurcated Enteral Extension Set Basic UDI - 506059088E/OSyringeActvG2 ELDISO-5 Enteral ISOSAF 5ml LDT ENFit Sterile Syringe EISO-5 Enteral ISOSAF 5ml ENFit Sterile Syringe EISO-10 Enteral ISOSAF 10ml ENFit Sterile Syringe EISO-20 Enteral ISOSAF 20ml ENFit Sterile Syringe EISO-35 Enteral ISOSAF 35ml ENFit Sterile Syringe EISO-60 Enteral ISOSAF 60ml ENFit Sterile Syringe ELDISO-PFC-6 Enteral ISOSAF 6ml LDT ENFit Sterile Syringe & PFC EISO-PFC-12 Enteral ISOSAF 12ml ENFit Sterile Syringe & PFC EISO-PFC-20 Enteral ISOSAF 20ml ENFit Sterile Syringe & PFC EISO-PFC-35 Enteral ISOSAF 35ml ENFit Sterile Syringe & PFC EISO-PFC-60 Enteral ISOSAF 60ml ENFit Sterile Syringe & PFC SELDISO-6 Enteral ISOSAF 6ml LDT ENFit O-Ring Sterile Syringe SEISO-12 Enteral ISOSAF 12ml ENFit O-Ring Sterile Syringe SEISO-20 Enteral ISOSAF 20ml ENFit O-Ring Sterile Syringe SEISO-35 Enteral ISOSAF 35ml ENFit O-Ring Sterile Syringe SEISO-60 Enteral ISOSAF 60ml ENFit O-Ring Sterile Syringe	Class IIa	N/A	GB19/9 63733 NB1639

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
SELDISO-PFC-6	Enteral ISOSAF 6ml LDT ENFit O-Ring Sterile Syringe & PFC			
SEISO-PFC-12	Enteral ISOSAF 12ml ENFit O-Ring Sterile Syringe & PFC			
SEISO-PFC-20	Enteral ISOSAF 20ml ENFit O-Ring Sterile Syringe & PFC			
SEISO-PFC-35	Enteral ISOSAF 35ml ENFit O-Ring Sterile Syringe & PFC			
SEISO-PFC-60	Enteral ISOSAF 60ml ENFit O-Ring Sterile Syringe & PFC			
ELDISO-5H	Enteral ISOSAF 5ml LDT ENFit HOME Sterile Syringe			
EISO-10H	Enteral ISOSAF 10ml ENFit HOME Sterile Syringe			
EISO-20H	Enteral ISOSAF 20ml ENFit HOME Sterile Syringe			
EISO-60H	Enteral ISOSAF 60ml ENFit HOME Sterile Syringe			
ELDISO-5H2	Enteral ISOSAF 5ml LDT ENFit HOME2 Sterile Syringe			
EISO-10H2	Enteral ISOSAF 10ml ENFit HOME2 Sterile Syringe			
EISO-20H2	Enteral ISOSAF 20ml ENFit HOME2 Sterile Syringe			
EISO-60H2	Enteral ISOSAF 60ml ENFit HOME2 Sterile Syringe			
EISO-5BNS-EU	Enteral ISOSAF 5ml ENFit BNS Syringe			
EISO-10BNS-EU	Enteral ISOSAF 10ml ENFit BNS Syringe			
EISO-20BNS-EU	Enteral ISOSAF 20ml ENFit BNS Syringe			
EISO-35BNS	Enteral ISOSAF 35ml ENFit BNS Syringe			
EISO-60BNS-EU	Enteral ISOSAF 60ml ENFit BNS Syringe			
ELDISO-SSD	Enteral ISOSAF 5ml LDT ENFit Sterile Syringe SD			
EISO-10SD	Enteral ISOSAF 10ml ENFit Sterile Syringe SD			
EISO-20SD	Enteral ISOSAF 20ml ENFit Sterile Syringe SD			
EISO-35SD	Enteral ISOSAF 35ml ENFit Sterile Syringe SD			
EISO-60SD	Enteral ISOSAF 60ml ENFit Sterile Syringe SD			
121824	D-3nteral 5ml LDT Single Use ENFit Sterile Syringe			
91421	D-3nteral 10ml Single Use ENFit Sterile Syringe			
91422	D-3nteral 20ml Single Use ENFit Sterile Syringe			
124823	D-3nteral 60ml Single Use ENFit Sterile Syringe			
157052	D-3nteral 5ml LDT Reusable ENFit Sterile Syringe			
105969	D-3nteral 10ml Reusable ENFit Sterile Syringe			
105968	D-3nteral 20ml Reusable ENFit Sterile Syringe			
123584	D-3nteral 60ml Reusable ENFit Sterile Syringe			
409106	Cenaman ENFit Syringe LDT 5ml			
409108-1	Cenaman ENFit Syringe 10ml			
409110-1	Cenaman ENFit Syringe 20ml – 100 units			
409110-3	Cenaman ENFit Syringe 20ml – 30 units			
409114-1	Cenaman ENFit Syringe 60ml Decentral			
409112-1	Cenaman ENFit Syringe 60ml Central			
Basic UDI – 506059088SyringeDriver99				
ENT575 Enteral Syringe Driver				
Basic UDI - 506059088StomaPlugU9				
EN-PLUG-S	Silicone plug set 4cm (Non-Sterile). Fr Size 10, 12, 14 and 16.			
EN-PLUG-L	Silicone plug set 7cm (Non-Sterile). Fr Size 10, 12, 14 and 16.			
EN-PLUG-XL	Silicone plug set 7cm (Non-Sterile). Fr Size 18 and 20.			
Basic UDI - 50560383WoundDrainVB				
MM50-02.008P	Safe-T-Vac 200ml kit with bottle, drain and tubing – 8Fr			
MM50-02.010P	Safe-T-Vac 200ml kit with bottle, drain and tubing – 10Fr			
MM50-04.010P	Safe-T-Vac 400ml kit with bottle, drain and tubing – 10Fr			

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
MM50-04.014P Safe-T-Vac 400ml kit with bottle, drain and tubing – 14Fr MM50-04.016P Safe-T-Vac 400ml kit with bottle, drain and tubing – 16Fr MM50-06.010P Safe-T-Vac 600ml kit with bottle, drain and tubing – 10Fr MM50-06.012P Safe-T-Vac 600ml kit with bottle, drain and tubing – 12Fr MM50-06.016P Safe-T-Vac 600ml kit with bottle, drain and tubing – 16Fr MM50-06.108P Safe-T-Vac 600ml kit with bottle, drain and tubing (with NRV) – 8 Fr MM50-06.110P Safe-T-Vac 600ml kit with bottle, drain and tubing (with NRV) – 10Fr MM50-06.112P Safe-T-Vac 600ml kit with bottle, drain and tubing (with NRV) – 12Fr MM50-06.114P Safe-T-Vac 600ml kit with bottle, drain and tubing (with NRV) – 14Fr MM50-06.116P Safe-T-Vac 600ml kit with bottle, drain and tubing (with NRV) – 16Fr Basic UDI - 50560383NeuraxialKK 15011010 Dash 6® NRFit Lock 1ml Syringe (Sterile) 15010010 Dash 6® NRFit Lock 1ml Syringe (BNS) 15011030 Dash 6® NRFit Lock 3ml Syringe (Sterile) 15010030 Dash 6® NRFit Lock 3ml Syringe (BNS) 15011050 Dash 6® NRFit Lock 5ml Syringe (Sterile) 15010050 Dash 6® NRFit Lock 5ml Syringe (BNS) 15011100 Dash 6® NRFit Lock 10ml Syringe (Sterile) 15010100 Dash 6® NRFit Lock 10ml Syringe (BNS) 15011200 Dash 6® NRFit Lock 20ml Syringe (Sterile) 15010200 Dash 6® NRFit Lock 20ml Syringe (BNS) 15011600 Dash 6® NRFit Lock 60ml Syringe (Sterile) 15010600 Dash 6® NRFit Lock 60ml Syringe (BNS) 15021010 Dash 6® NRFit Slip 1ml Syringe (Sterile) 15020010 Dash 6® NRFit Slip 1ml Syringe (BNS) 15021030 Dash 6® NRFit Slip 3ml Syringe (Sterile) 15020030 Dash 6® NRFit Slip 3ml Syringe (BNS) 15021050 Dash 6® NRFit Slip 5ml Syringe (Sterile) 15020050 Dash 6® NRFit Slip 5ml Syringe (BNS) 15021100 Dash 6® NRFit Slip 10ml Syringe (Sterile) 15020100 Dash 6® NRFit Slip 10ml Syringe (BNS) 15021200 Dash 6® NRFit Slip 20ml Syringe (Sterile) 15020200 Dash 6® NRFit Slip 20ml Syringe (BNS) 15090002 Introducer Needle 18G 38mm (BNS) Basic UDI - 50560383SuctionYD TT01-05-035 TenderTip Open Suction Catheter 5ch x 35cm TT01-05-050 TenderTip Open Suction Catheter 5ch x 50cm TT01-06-035 TenderTip Open Suction Catheter 6ch x 35cm TT01-06-050 TenderTip Open Suction Catheter 6ch x 50cm TT01-07-035 TenderTip Open Suction Catheter 7ch x 35cm TT01-07-050 TenderTip Open Suction Catheter 7ch x 50cm TT01-08-035 TenderTip Open Suction Catheter 8ch x 35cm TT01-08-050 TenderTip Open Suction Catheter 8ch x 50cm TT01-10-035 TenderTip Open Suction Catheter 10ch x 35cm TT01-10-050 TenderTip Open Suction Catheter 10ch x 50cm TT01-10-060 TenderTip Open Suction Catheter 10ch x 60cm TT01-12-050 TenderTip Open Suction Catheter 12ch x 50cm			

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
TT01-12-060	TenderTip Open Suction Catheter 12ch x 60cm			
TT01-14-060	TenderTip Open Suction Catheter 14ch x 60cm			
TT01-16-060	TenderTip Open Suction Catheter 16ch x 60cm			
TT02-05-E31	TenderTip Closed Suction Set 24hr, 5ch Neonatal			
TT02-06-E31	TenderTip Closed Suction Set 24hr, 6ch Neonatal			
TT02-07-E31	TenderTip Closed Suction Set 24hr, 7ch Neonatal			
TT02-08-E31	TenderTip Closed Suction Set 24hr, 8ch Neonatal			
TT02-06-P31	TenderTip Closed Suction Set 24hr, 6ch Paediatric			
TT02-07-P31	TenderTip Closed Suction Set 24hr, 7ch Paediatric			
TT02-08-P31	TenderTip Closed Suction Set 24hr, 8ch Paediatric			
TT02-10-E54-N	TenderTip Closed Suction Set 24hr, 10ch Endotracheal			
TT02-12-E54-N	TenderTip Closed Suction Set 24hr, 12ch Endotracheal			
TT02-12-T34-N	TenderTip Closed Suction Set 24hr, 12ch Tracheal			
TT02-14-E54-N	TenderTip Closed Suction Set 24hr, 14ch Endotracheal			
TT02-14-T34-N	TenderTip Closed Suction Set 24hr, 14ch Tracheal			
TT03-12-E54-N	TenderTip Closed Suction Set 72hr, 12ch Endotracheal			
TT03-12-T34-N	TenderTip Closed Suction Set 72hr, 12ch Tracheal			
TT03-14-E54-N	TenderTip Closed Suction Set 72hr, 14ch Endotracheal			
TT03-14-T34-N	TenderTip Closed Suction Set 72hr, 14ch Tracheal			
TT04-12-E56	TenderTip Plus Closed Suction Set 72hr, 12ch Endotracheal			
TT04-14-E56	TenderTip Plus Closed Suction Set 72hr, 14ch Endotracheal			
TT04-12-T36	TenderTip Plus Closed Suction Set 72hr, 12ch Tracheal			
TT04-14-T36	TenderTip Plus Closed Suction Set 72hr, 14ch Tracheal			
CTY516MFV	CareTip Yankauer Suction Handle 5mm/16Fr Flexible, Short Mini, With Vacuum Control			
CTY516MRV	CareTip Yankauer Suction Handle 5mm/16Fr Rigid, Short Mini, With Vacuum Control			
CTY618RF	CareTip Yankauer Suction Handle 6mm/18Fr Flexible, Regular, No Vacuum Control			
CTY618RR	CareTip Yankauer Suction Handle 6mm/18Fr Rigid, Regular, No Vacuum Control			
CTY618RFV	CareTip Yankauer Suction Handle 6mm/18Fr Flexible, Regular, With Vacuum Control			
CTY618RRV	CareTip Yankauer Suction Handle 6mm/18Fr Rigid, Regular, With Vacuum Control			
CTY822HF	CareTip Yankauer Suction Handle 7mm/22Fr Flexible, High, No Vacuum Control			
CTY822HR	CareTip Yankauer Suction Handle 7mm/22Fr Rigid, High, No Vacuum Control			
CTY822BR	CareTip Yankauer Suction Handle 8mm/24Fr Rigid, Bulbous, No Vacuum Control			
CTY822BRV	CareTip Yankauer Suction Handle 8mm/24Fr Rigid, Bulbous, Vacuum Control			
CTY516MR	CareTip Yankauer, 5mm (16Fr), rigid, short mini, no vacuum control			
CTY516MF	CareTip Yankauer, 5mm (16Fr), flexible, short mini, no vacuum control			
MC01.14.010	CareTip MiniCath, 14ch, 10cm			

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
DC01.06.015	CareTip MiniCath Delicate, 6ch, 15cm			
DC01.07.015	CareTip MiniCath Delicate, 7ch, 15cm			
DC01.08.015	CareTip MiniCath Delicate, 8ch, 15cm			
DC01.10.015	CareTip MiniCath Delicate, 10ch, 15cm			
DC01.12.015	CareTip MiniCath Delicate, 12ch, 15cm			
Basic UDI - 506059088E/OSyringe4J		Class I Sterile & Measuring	N/A	GB19/9 63733 NB1639
EISO-1	Enteral ISOSAF 1ml ENFit Sterile Syringe			
EISO-3	Enteral ISOSAF 3ml ENFit Sterile Syringe			
ELDISO-1	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe			
ELDISO-3	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe			
OS-1	Oral Caretip 1ml Sterile Syringe			
OS-2	Oral Caretip 2.5ml Sterile Syringe			
OS-5	Oral Caretip 5ml Sterile Syringe			
OS-10	Oral Caretip 10ml Sterile Syringe			
OS-20	Oral Caretip 20ml Sterile Syringe			
EISO-100	Enteral ISOSAF 100ml ENFit Sterile Syringe			
ELDISO-PFC-1	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe & PFC			
ELDISO-PFC-3	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe & PFC			
SELDISO-PFC-1	Enteral ISOSAF 1ml LDT ENFit O-Ring Sterile Syringe & PFC			
SELDISO-PFC-3	Enteral ISOSAF 3ml LDT ENFit O-Ring Sterile Syringe & PFC			
SELDISO- 1	Enteral ISOSAF 1ml LDT ENFit O-Ring Sterile Syringe			
SELDISO- 3	Enteral ISOSAF 3ml LDT ENFit O-Ring Sterile Syringe			
ELDISO-1H	Enteral ISOSAF 1ml LDT ENFit HOME Sterile Syringe			
ELDISO-3H	Enteral ISOSAF 3ml LDT ENFit HOME Sterile Syringe			
ELDISO-1H2	Enteral ISOSAF 1ml LDT ENFit HOME2 Sterile Syringe			
ELDISO-2.5H2	Enteral ISOSAF 2.5ml LDT ENFit HOME2 Sterile Syringe			
EISO-100H2	Enteral ISOSAF 100ml ENFit HOME2 Sterile Syringe			
CT60	60ml Sterile Catheter Tip Syringe			
ELDISO-1SD	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe SD			
ELDISO-3SD	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe SD			
116327	D-3nteral 1ml LDT Single Use ENFit Sterile Syringe			
116326	D-3nteral 2.5ml LDT Single Use ENFit Sterile Syringe			
105967	D-3nteral 100ml Single Use ENFit Sterile Syringe			
157057	D-3nteral 1ml LDT Reusable ENFit Sterile Syringe			
157053	D-3nteral 2.5ml LDT Reusable ENFit Sterile Syringe			
409102	Cenaman ENFit Syringe LDT 1ml			
409104	Cenaman ENFit Syringe LDT 2.5ml			
409116	Cenaman ENFit Syringe 100ml			
Basic UDI - 506059088EntCareFeedNM		Class I Sterile	N/A	NB1639 GB19/9 63732 GB19/9 63732 GB19/9 63733 GB19/9 63732
YPA-ISO Y Port Adaptor				
Basic UDI - 506059088E/OSyringe4J				
PFC-100	Sterile Push Fit Cap (PFC) for Oral & Enteral Syringes			
EMBTC-50	Sterile ENFit Bottle Transfer Cap			
ECISO	Sterile Enteral Syringe Cap (Male ENFit Connector)			
ECISO-10	Sterile Enteral Syringe Cap (Male ENFit Connector) – 10 per bag			
FNISO-38	Sterile Enteral ISOSAF 5µm Filter Needle 18G x 38mm			
FNISO-50	Sterile Enteral ISOSAF 5µm Filter Needle 18G x 50mm			

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/ device	MDD Certificate Ref (s) & NB ID
MSISO-50P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 50mm			GB19/9
MSISO-100P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 100mm			63732
MSISO-150P	Sterile Enteral ISOSAF Medicine Straw 8Fr x 150mm			GB19/9
NNS05.40	Nursing Support Tube 5Fr x 40cm			63732
119490	Sterile Enteral D-3nteral Drawing Up Straw 100mm			GB19/9
119489	Sterile Enteral D-3nteral Drawing Up Straw 150mm			63733
119488	Sterile Enteral D-3nteral Syringe Cap			
9000793	Sterile ProNeo Bottle insert, non-removable 17-20.5mm			
9000794	Sterile ProNeo Bottle insert, non-removable 12-15mm			
9000795	Sterile ProNeo Bottle insert, non-removable 14-16.5mm			
9000796	Sterile ProNeo Bottle insert, non-removable 19-25mm			
9000797	Sterile ProNeo Bottle insert, non-removable 24-26mm			
7752012	Sterile ProNeo Sampling Cannula 5cm			
7752019	Sterile ProNeo Sampling Straw 5cm			
7752017	Sterile ProNeo Sampling Straw 10cm			
7752016	Sterile ProNeo Sampling Straw 15cm			
Basic UDI - 506059088EntDrainBagVH				
DBISO-50	50ml EVA Enteral Drainage Bag with ENFit Connector			
DBISO-100	100ml EVA Enteral Drainage Bag with ENFit Connector			
DBISO-250	250ml EVA Enteral Drainage Bag with ENFit Connector			
DBISON-500	500ml EVA Enteral Drainage Bag with ENFit Connector			
DBISO-500	500ml EVA Enteral Drainage Bag with Funnel Connector			
DBISO-1000	1000ml EVA Enteral Drainage Bag with Funnel Connector			
VB-250	250ml Vent Bag			
Basic UDI - 50560383WoundDrainVB				
CDB-001	Chest Drain Bottle, 1800ml capacity			
CDT-001	Chest Drain Tubing, 1.5m, single			
CDTY-001	Chest Drain Tubing, Y-set			
MM50-02.200P	Safe-T-Vac 200ml ward replacement bottle			
MM50-04.200P	Safe-T-Vac 400ml ward replacement bottle			
MM50-06.200P	Safe-T-Vac 600ml ward replacement bottle			
Basic UDI - 50560383NeuraxialAccSM3U				
15041001	DASH 6® NRFit Syringe Cap			
15111001	DASH 6® NRFit Needle Hub Cap			
15171001	DASH 6® NRFit Syringe to Syringe Connector			
15231022	DASH 6® NRFit 0.22µm Bacterial Filter			
15281100	DASH 6® NRFit 5µm Drawing up Filter Straw (100mm)			
15291050	DASH 6® NRFit 5µm Blunt Drawing up Filter Needle (18G x 50mm)			
15311022	DASH 6® NRFit 0.22µm Epidural Flat Filter			
15461010	DASH 6® NRFit Extension Set with clamp (10cm) (Sterile)			
15461020	DASH 6® NRFit Extension Set with clamp (20cm) (Sterile)			
15461125	DASH 6® NRFit Extension Set with clamp (125cm) (Sterile)			
15491050	DASH 6® NRFit Blunt Drawing up Needle (18G x 50mm)			
15241001	DASH 6® NRFit™ 3-Way Stopcock (Sterile)			
Basic UDI - 506059088E/OSyringe4J		Class I Measuring	N/A	GB19/9
ELDISO-1BNS-EU	Enteral ISOSAF 1ml LDT ENFit Sterile Syringe & PFC			63733
ELDISO-3BNS-EU	Enteral ISOSAF 3ml LDT ENFit Sterile Syringe & PFC			NB1639

Device name / Basic UDI-DI (under MDR application)		MDR Device classification	ID of the corresponding MDD/device	MDD Certificate Ref (s) & NB ID
ABLDS-PFCO-1-EU	Enteral ISOSAF Amber 1ml LDT BNS Syringe & Orange PFC			
ABLDS-PFCO-3-EU	Enteral ISOSAF Amber 3ml LDT BNS Syringe & Orange PFC			
ABS-PFCO-5-EU	Enteral ISOSAF Amber 5ml BNS Syringe & Orange PFC			
ABS-PFCO-10-EU	Enteral ISOSAF Amber 10ml BNS Syringe & Orange PFC			
ABS-PFCO-20-EU	Enteral ISOSAF Amber 20ml BNS Syringe & Orange PFC			
ABS-PFCO-35-EU	Enteral ISOSAF Amber 35ml BNS Syringe & Orange PFC			
ABS-PFCO-60-EU	Enteral ISOSAF Amber 60ml BNS Syringe & Orange PFC			
ABOSPFCO-1-500NS	Box of Oral Amber 1ml BNS Syringes & Orange PFC in Separate Bags			
ABOSPFCO-3-500NS	Box of Oral Amber 3ml BNS Syringes & Orange PFC in Separate Bags			
ABOSPFCO-5-500NS	Box of Oral Amber 5ml BNS Syringes & Orange PFC in Separate Bags			
ABOSPFCO-10-500NS	Box of Oral Amber 10ml BNS Syringes & Orange PFC in Separate Bags			
ABOSPFCO-20-200NS	Box of Oral Amber 20ml BNS Syringes & Orange PFC in Separate Bags			
Basic UDI - 506059088GastrostomyXH G-PAKISOGastrostomy Procedure Pack		Article 12 Procedure Pack	N/A	GB19/9 63732 NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/23	Version 1	Initial issue