

Nürnberg, März 2026

## **Übergangsbestimmungen der EU-Medizinprodukteverordnung (MDR) – Weiterhin gültiges Inverkehrbringen von Produkten mit abgelaufenem Zertifikat**

Sehr geehrte Damen und Herren,

wie Sie wissen, befindet sich die europäische Medizinproduktebranche derzeit in der Übergangsphase zur vollständigen Anwendung der EU-Medizinprodukteverordnung (EU) 2017/745 (MDR). Die MDR sieht spezifische **Übergangsbestimmungen** vor, die es ermöglichen, bestimmte Produkte weiterhin in Verkehr zu bringen, auch wenn die entsprechenden Zertifikate nach der Richtlinie 93/42/EWG (MDD) bereits abgelaufen sind.

Gemäß den geltenden Übergangsregelungen dürfen Produkte mit einem abgelaufenen Zertifikat weiterhin auf dem Markt bereitgestellt werden, **sofern eine gültige, schriftliche Vereinbarung mit der zuständigen Benannten Stelle vor dem Ablauf der ursprünglichen Zertifizierung abgeschlossen wurde**. Diese schriftliche Übereinkunft bestätigt, dass das Produkt sich im MDR-Konformitätsbewertungsverfahren befindet und alle Voraussetzungen der Übergangsbestimmungen erfüllt werden.

Wir möchten Ihnen hiermit bestätigen, dass diese Voraussetzungen für die betroffenen Produkte unseres Hauses erfüllt sind. Damit ist das weitere Inverkehrbringen rechtlich zulässig und vollständig MDR-konform.

Im Anschluss an dieses Schreiben finden Sie folgende Dokumente:

1. **Schriftliche Vereinbarung mit der Benannten Stelle**
2. **Das abgelaufene Zertifikat / die abgelaufene Konformitätserklärung**

Diese Unterlagen dienen Ihrer Transparenz, Dokumentation und Nachweisführung gegenüber Behörden oder internen Qualitätssystemen.

Für Rückfragen stehen wir Ihnen selbstverständlich jederzeit gerne unter [medizinprodukte@danone.com](mailto:medizinprodukte@danone.com) zur Verfügung.

Mit freundlichen Grüßen,

Danone Deutschland GmbH

**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](mailto: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
<b>Basic UDI - 506059088EntFeedGT</b>	Class IIb	N/A	GB19/9 63733 NB1639
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			

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			
<b>Basic UDI - 50560383BifurcateNeedleXL</b> 14011001 Bifurcated Needle			
<b>Basic UDI - 50560383PessaryVA</b> 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			
<b>Basic UDI - 506059088EntCareFeedNM</b> 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 <b>Basic UDI - 506059088E/OSyringeActvG2</b> 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			
SEISO-PFC-12			
SEISO-PFC-20			
SEISO-PFC-35			
SEISO-PFC-60			
ELDISO-5H			
EISO-10H			
EISO-20H			
EISO-60H			
ELDISO-5H2			
EISO-10H2			
EISO-20H2			
EISO-60H2			
EISO-5BNS-EU			
EISO-10BNS-EU			
EISO-20BNS-EU			
EISO-35BNS			
EISO-60BNS-EU			
ELDISO-5SD			
EISO-10SD			
EISO-20SD			
EISO-35SD			
EISO-60SD			
121824			
91421			
91422			
124823			
157052			
105969			
105968			
123584			
409106			
409108-1			
409110-1			
409110-3			
409114-1			
409112-1			
<b>Basic UDI – 506059088SyringeDriver99</b>			
ENT575 Enteral Syringe Driver			
<b>Basic UDI - 506059088StomaPlugU9</b>			
EN-PLUG-S			
EN-PLUG-L			
EN-PLUG-XL			
<b>Basic UDI - 50560383WoundDrainVB</b>			
MM50-02.008P			
MM50-02.010P			
MM50-04.010P			

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			
<b>Basic UDI - 50560383NeuraxialKK</b>			
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)			
<b>Basic UDI - 50560383SuctionYD</b>			
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			
<b>Basic UDI - 506059088E/OSyringe4J</b> 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	Class I Sterile & Measuring	N/A	GB19/9 63733 NB1639
<b>Basic UDI - 506059088EntCareFeedNM</b> YPA-ISO Y Port Adaptor <b>Basic UDI - 506059088E/OSyringe4J</b> 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	Class I Sterile	N/A	NB1639 GB19/9 63732 GB19/9 63732 GB19/9 63733 GB19/9 63732

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			
<b>Basic UDI - 506059088EntDrainBagVH</b>			
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			
<b>Basic UDI - 50560383WoundDrainVB</b>			
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			
<b>Basic UDI - 50560383NeuraxialAccSM3U</b>			
15041001 DASH 6 <sup>®</sup> NRFit Syringe Cap			
15111001 DASH 6 <sup>®</sup> NRFit Needle Hub Cap			
15171001 DASH 6 <sup>®</sup> NRFit Syringe to Syringe Connector			
15231022 DASH 6 <sup>®</sup> NRFit 0.22µm Bacterial Filter			
15281100 DASH 6 <sup>®</sup> NRFit 5µm Drawing up Filter Straw (100mm)			
15291050 DASH 6 <sup>®</sup> NRFit 5µm Blunt Drawing up Filter Needle (18G x 50mm)			
15311022 DASH 6 <sup>®</sup> NRFit 0.22µm Epidural Flat Filter			
15461010 DASH 6 <sup>®</sup> NRFit Extension Set with clamp (10cm) (Sterile)			
15461020 DASH 6 <sup>®</sup> NRFit Extension Set with clamp (20cm) (Sterile)			
15461125 DASH 6 <sup>®</sup> NRFit Extension Set with clamp (125cm) (Sterile)			
15491050 DASH 6 <sup>®</sup> NRFit Blunt Drawing up Needle (18G x 50mm)			
15241001 DASH 6 <sup>®</sup> NRFit™ 3-Way Stopcock (Sterile)			
<b>Basic UDI - 506059088E/OSyringe4J</b>			
ELDISO-1BNS-EU Enteral ISOSAF 1ml LDT ENFit Sterile Syringe & PFC	Class I Measuring	N/A	GB19/9
ELDISO-3BNS-EU Enteral ISOSAF 3ml LDT ENFit Sterile Syringe & PFC			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
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			
<b>Basic UDI - 506059088GastrostomyXH</b> 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

<b>Declaration of Conformity</b>		
<b>Technical file</b>	Enteral / Oral Syringe System	
<b>Document Reference</b>	DOC-E-002-NUTRICIA-SYRINGES	
<b>Issue</b>	3.0	Page 1 of 3



## 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>	Enteral / Oral Syringes
<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 Directive 93/42/EEC
<b>Classification Rule</b>	Rule 2, Annex IX, for Class IIa and Class I Sterile & Measuring Devices
<b>Assessment Route</b>	Annex II for Class IIa Devices Annex V for Class I Sterile & Measuring Devices
<b>Certificate Number (Issue)</b>	Annex II Certificate: GB19/963733 (Issue 4)

<b>Declaration of Conformity</b>		
<b>Technical file</b>	Enteral / Oral Syringe System	
<b>Document Reference</b>	DOC-E-002-NUTRICIA-SYRINGES	
<b>Issue</b>	3.0	Page 2 of 3

<b>Notified Body</b>	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium  Notified Body Number: 1639
<b>EU Authorized Representative</b>	QualRep Services BV Utrechtseweg 310 B-42 6800 AR Arnhem The Netherlands

Signed:

Position: Regulatory Affairs Manager

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.

<b>Declaration of Conformity</b>		
<b>Technical file</b>	Enteral / Oral Syringe System	
<b>Document Reference</b>	DOC-E-002-NUTRICIA-SYRINGES	
<b>Issue</b>	3.0	Page <b>3</b> of <b>3</b>

## Appendix

<b>Product Catalogue Number</b>	<b>Product Description</b>	<b>Classification</b>
105969	D-3nteral 10ml reusable ENFit syringe	Ila
105968	D-3nteral 20ml reusable ENFit syringe	Ila
123584	D-3nteral 60ml reusable ENFit syringe	Ila
116327	D-3nteral 1ml Low Dose Single Use ENFit Syringe	I Sterile & Measuring
121824	D-3nteral 5ml Low Dose Single Use ENFit Syringe	Ila
91421	D-3nteral 10ml Single Use ENFit Syringe	Ila
116326	D-3nteral 2.5ml Low Dose Single Use ENFit Syringe	I Sterile & Measuring
91422	D-3nteral 20ml Single Use ENFit Syringe	Ila
124823	D-3nteral 60ml Single Use ENFit Syringe	Ila
105967	D-3nteral 100ml Single Use ENFit Syringe	I Sterile & Measuring
164068	ENFIT ISOSAF 3ml Single Use ENFit Syringe	I Sterile & Measuring
164062	ENFIT ISOSAF 10ml Single Use ENFit Syringe	Ila
164061	ENFIT ISOSAF 100ml Single Use ENFit Syringe	I Sterile & Measuring
13021017	ISOSAF 1ml Low Dose Home 2 ENFit Syringe	I Sterile & Measuring
13021127	ISOSAF 2.5ml Low Dose Home 2 ENFit Syringe	I Sterile & Measuring
13021055	ISOSAF 5ml Low Dose Home 2 ENFit Syringe	Ila