

Flexicare Medical Limited EU Declaration of Conformity

This EU Declaration of Conformity has been issued under the sole responsibility of the manufacturer:

Flexicare Medical Limited
Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK.
Company Registration Number: 2428573

Flexicare Medical Limited declares that the devices listed below meet the provisions of the European Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC.

Conformity assessment route: Annex V
Certificate Number(s): GB19/964677
EU Single Registration Number (SRN): GB-MF-000034163

The Notified Body responsible for conformity assessment is SGS Belgium NV (CE 1639), Noorderlaan 87, BE-2030 Antwerpen. Belgium.

Flexicare Medical Limited declares that the devices listed below and identified as applicable meet the provisions of Directive 2011/65/EU (as amended) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Flexicare has appointed its Germany based facility as its Authorised Representative within the European Union, with registered address as follows:

Flexicare Deutschland GmbH,
Ohlenhohnstrasse 34,
53819 Neunkirchen-Seelscheid,
Germany
SRN: DE-AR-000029825

For and on behalf of Flexicare Medical Limited,



Dr Gurge Phull
RA/QA Director

Reference:	DOC-000002/25
Date of Issue:	19 Aug 2024
Place of Issue:	Flexicare Medical Limited Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK.

Declaration of Conformity for Class Is & m Devices

Relevant Intended Purpose available in Annex A

TECHNICAL FILE	PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Technical File: 003						
003	1005-25	Suction Tube 0.5m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1020-25	Suction Tube 2m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1020-6	Suction Tube 2m with F/F Connector 6mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1024-25	Suction Tube 2.4m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1027-25	Suction Tube 2.7m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1030-25	Suction Tube 3m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1030-5	Suction Tube 3m with F/F Connector 5mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1030-6	Suction Tube 3m with F/F Connector 6mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1035-6	Suction Tube 3.5m with F/F Connector 6mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1035-25	Suction Tube 3.5m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1037-25	Suction Tube 3.7m with F/F Connector 7mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1045-6	Suction Tube 4.5m with F/F Connector 6mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
003	1060-6	Suction Tube 6.0m with F/F Connector 6mm ID Sterile	Class I Sterile (Rule 1)	16779	Suction/irrigation tubing, single-use	N
Technical File 019a						
Flexicare Range						
19a	00-1503L	Leg Bag 500ml Short Tube without Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2503L	Leg Bag 500ml Long Tube without Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1352	Leg Bag 350ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1352H	Leg Bag 350ml Short Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2352	Leg Bag 350ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2352U	Leg Bag 350ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2352H	Leg Bag 350ml Long Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1502	Leg Bag 500ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2502	Leg Bag 500ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N

19a	00-2502U	Leg Bag 500ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2502H	Leg Bag 500ml Long Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-3502	Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-3502U	Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-3752U	Leg Bag 750ml Extra Long Adjustable Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1752	Leg Bag 750ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1752U	Leg Bag 750ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1752H	Leg Bag 750ml Short Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1752HNS	Leg Bag 750ml Short Tube without Leg Strap Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2752	Leg Bag 750ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2752H	Leg Bag 750ml Long Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1502G	Leg Bag 500ml Short Tube with Fabric Backing + Non-Latex Gloves	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-1502H	Leg Bag 500ml Short Tube Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-2502G	Leg Bag 500ml Long Tube with Fabric Backing and 1 Pair Non-Latex Gloves	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
Discreet Range						
19a	00-5352	Discreet Leg Bag 350ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6352	Discreet Leg Bag 350ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-5502	Discreet Leg Bag 500ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-5502U	Discreet Leg Bag 500ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-5503	Discreet Leg Bag 500ml Short Tube without Fabric Backing Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6502	Discreet Leg Bag 500ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6503	Discreet Leg Bag 500ml Long Tube without Fabric Backing Sterile	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6504	Discreet Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6504U	Discreet Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-5752	Discreet Leg Bag 750ml Short Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6752	Discreet Leg Bag 750ml Long Tube with Fabric Backing	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-5502G	Discreet Leg Bag 500ml Short Tube with Fabric Backing and 1 Pair Non-Latex Gloves	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
19a	00-6502G	Discreet Leg Bag 500ml Long Tube with Fabric Backing and 1 Pair Non-Latex Gloves	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N
Kits						

19a	00-0045	Kit A Drainable Night Bag Home Pack with 2 x F4L and 1 x 500ml Short Tube Leg Bag	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N	
19a	00-0046	Kit B Drainable Night Bag Home Pack with 2 x F4L and 1 x 500ml Long Tube Leg Bag	Class I Sterile (Rule 1)	58923	Wearable urine collection bag, open-ended	N	
Technical File 019b							
19b	00-1200	F4 2L Drainable Bag with T-Tap	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1201	F4 2L Drainable Bag with Lever Tap	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1201U	F4 2L Drainable Bag with Lever Tap	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1202LEDUT	F4 2L Drainable Bag with T-Tap Non Sterile (Omnimedical)	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1204	F4 2L Drainable Bag with T-Tap	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1204H	F4 2L Drainable Bag with T-Tap Sterile	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1204L	F4 2L Drainable Bag with Lever Tap	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1204LC	F4 2L Drainable Bag with Clamp Sterile	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1205	F4 2L Drainable Bag with T-Tap with Bedhangers	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1205U	F4 2L Drainable Bag with T-Tap with Bedhangers	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1207L	F4 2L Drainable Bag with Side Lever Tap and Pouch Tap Storage	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1208	Post Operative 2L Drainable Bag with Drip Chamber and Hanger	Class I Sterile (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1208U	Post Operative 2L Drainable Bag with Drip Chamber and Hanger	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
19b	00-1350M	Mermaid Medical Drainage Bag 350ml	Class I Sterile (Rule I)	58921	Non-wearable urine collection bag, open-ended	N	
Technical File 019b							
019b	00-2202	F2 2L Non-Drainable Bag	Class I Sterile (Rule 1)	58917	Non-wearable urine collection bag, closed-ended	N	
Technical File 027							
027	C0300	PuraSpec Small with Lock	Class I Sterile (Rule 5)	37468	Vaginal speculum, single-use	N	
027	C0301	PuraSpec Medium with Lock	Class I Sterile (Rule 5)	37468	Vaginal speculum, single-use	N	
027	C0302	PuraSpec Large with Lock	Class I Sterile (Rule 5)	37468	Vaginal speculum, single-use	N	
Technical File 028							
28	038-05-602	VentiSorb Carbon Dioxide Absorbent Pink to White 2 x 4.5Kg	Pink to White	Class IIa (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
28	038-05-602U	VentiSorb Carbon Dioxide Absorbent Pink to White 2 x 4.5Kg	Pink to White	Class IIa (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
28	038-05-604	VentiSorb Carbon Dioxide Absorbent White to Violet 2 x 4.5Kg	White to Violet	Class IIa (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
28	038-05-604U	VentiSorb Carbon Dioxide Absorbent White to Violet 2 x 4.5Kg	White to Violet	Class IIa (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
Technical File 30a							
30a	038-93-890	Guedel Airway Length 3cm Size 0000	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N	
30a	038-93-900	Guedel Airway Length 4cm Size 000	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N	
30a	038-92-902	Guedel Airway Length 5cm Size 00	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N	

30a	038-92-900	Guedel Airway Length 6cm Size 0	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-910	Guedel Airway Length 7cm Size 1	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-910 INA	Guedel Airway Length 7cm Size 1	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-920	Guedel Airway Length 8cm Size 2	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-920 INA	Guedel Airway Length 8cm Size 2	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-930	Guedel Airway Length 9cm Size 3	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-930 INA	Guedel Airway Length 9cm Size 3	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-940	Guedel Airway Length 10cm Size 4	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-940 INA	Guedel Airway Length 10cm Size 4	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-945	Guedel Airway Length 11 cm Size 5	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-950	Guedel Airway Length 12cm Size 6	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-93-890U	Guedel Airway Length 3cm Size 0000	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-93-900U	Guedel Airway Length 4cm Size 000	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-93-900 INA	Guedel Airway Length 4cm Size 000	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-92-902U	Guedel Airway Length 5cm Size 00	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-92-902 INA	Guedel Airway Length 5cm Size 00	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-92-900U	Guedel Airway Length 6cm Size 0	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-92-900 INA	Guedel Airway Length 6cm Size 0	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-910U	Guedel Airway Length 7cm Size 1	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-920U	Guedel Airway Length 8cm Size 2	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-930U	Guedel Airway Length 9cm Size 3	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-940U	Guedel Airway Length 10cm Size 4	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-945U	Guedel Airway Length 11 cm Size 5	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-950U	Guedel Airway Length 12cm Size 6	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-000U	Guedel Airway Length 4cm Size 000 Sterile	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-001U	Guedel Airway Length 5cm Size 00 with Blue Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-011U	Guedel Airway Length 6cm Size 0 with Black Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-100	Guedel Airway Length 7cm Size 1 with White Bite Block Ste	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-100U	Guedel Airway Length 7cm Size 1 with White Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-200U	Guedel Airway Length 8cm Size 2 with Green Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-300U	Guedel Airway Length 9cm Size 3 with Orange Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
30a	038-91-400U	Guedel Airway Length 10cm Size 4 with Red Bite Block	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
Technical File:030c						
030c	038-90-909	Williams Airway Length 9cm	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
030c	038-90-910	Williams Airway Length 10cm	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
030c	038-90-909U	Williams Airway Length 9cm	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
030c	038-90-910U	Williams Airway Length 10cm	Class I Sterile (Rule 5)	42424	Oropharyngeal airway, single-use	N
Technical File:040						
040	00-1227	UriMeter 1.5m Inlet Tube Sterile	Class I Sterile, Measuring (Rule 1)	32072	Urine flowmeter, single-use	N
040	00-1227U	UriMeter 1.5m Inlet Tube Sterile	Class I Sterile, Measuring (Rule 1)	32072	Urine flowmeter, single-use	N
Technical File:056c						
56c	030-615STR	Red Safety Cap for 15mm Circuit	Class I Sterile (Rule 1)	61347	Tube/mask breathing circuit connector, single-use, sterile	N

Technical File:108						
108	038-968-033	Bougie / Introducer OD 3.3mm (10Ch) 700mm	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
108	038-968-050	Bougie / Introducer OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
108	038-968-033U	Bougie / Introducer OD 3.3mm (10Ch) 700mm	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
108	038-968-050U	Bougie / Introducer OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
108	038-968-033J	Bougie/Introducer Od 3.3mm (10ch)X 700mm - Sterile	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
	038-968-050J	Bougie/Introducer Od 5.0mm (15ch)X 700mm - Sterile	Class I Sterile (Rule 5)	41829	Endotracheal tube introducer, single-use	N
Technical File:109						
109	038-967-022	Intubating Stylet OD 2.2mm (6Ch) 225mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-022 MEDI	Intubating Stylet OD 2.2mm (6Ch) 225mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-040	Intubating Stylet OD 4.0mm (12Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-050	Intubating Stylet OD 5.0mm (15Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-050 MEDI	Intubating Stylet OD 5.0mm (15Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-140	Intubating Stylet OD 4.0mm (12Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-140 MEDI	Intubating Stylet OD 4.0mm (12Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-150	Intubating Stylet OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-150 MEDI	Intubating Stylet OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-022U	Intubating Stylet OD 2.2mm (6Ch) 225mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-040 MEDI	Intubating Stylet OD 4.0mm (12Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-040U	Intubating Stylet OD 4.0mm (12Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-050U	Intubating Stylet OD 5.0mm (15Ch) 405mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-140U	Intubating Stylet OD 4.0mm (12Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-150U	Intubating Stylet OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-022J	STYLET OD 2.2MM (6CH) 225MM PAEDIATRIC - STERILE	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	038-967-050J	Intubating Stylet OD 5.0mm (15Ch) 700mm	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	040-08-2024	ProVu Rigid Stylet - Medium	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	040-08-2024U	ProVu Rigid Stylet - Medium	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
109	040-08-2030	ProVu Rigid Stylet - Large	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N

109	040-08-2030U	ProVu Rigid Stylet - Large	Class I Sterile (Rule 5)	37469	Artificial airway stylet, single-use	N
Technical File: 114						
114	038-95-004	NasoSafe Nasopharyngeal Airway ID Size 4.0mm 20 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-004 INA	NasoSafe Nasopharyngeal Airway ID Size 4.0mm 20 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-045	NasoSafe Nasopharyngeal Airway ID Size 4.5mm 22 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-045 INA	NasoSafe Nasopharyngeal Airway ID Size 4.5mm 22 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-005	NasoSafe Nasopharyngeal Airway ID Size 5.0mm 24 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-005 INA	NasoSafe Nasopharyngeal Airway ID Size 5.0mm 24 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-055	NasoSafe Nasopharyngeal Airway ID Size 5.5mm 26 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-055 INA	NasoSafe Nasopharyngeal Airway ID Size 5.5mm 26 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-006	NasoSafe Nasopharyngeal Airway ID Size 6.0mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-006 INA	NasoSafe Nasopharyngeal Airway ID Size 6.0mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-065	NasoSafe Nasopharyngeal Airway ID Size 6.5mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-065 INA	NasoSafe Nasopharyngeal Airway ID Size 6.5mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007	NasoSafe Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007 INA	NasoSafe Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007SP	NasoSafe Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-075	NasoSafe Nasopharyngeal Airway ID Size 7.5mm 32 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-075 INA	NasoSafe Nasopharyngeal Airway ID Size 7.5mm 32 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-008	NasoSafe Nasopharyngeal Airway ID Size 8.0mm 34 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-008 INA	NasoSafe Nasopharyngeal Airway ID Size 8.0mm 34 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-085	NasoSafe Nasopharyngeal Airway ID Size 8.5mm 36 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-009	NasoSafe Nasopharyngeal Airway ID Size 9.0mm 38 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-004U	NasoSafe Nasopharyngeal Airway ID Size 4.0mm 20 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-045U	NasoSafe Nasopharyngeal Airway ID Size 4.5mm 22 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-005U	NasoSafe Nasopharyngeal Airway ID Size 5.0mm 24 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-055U	NasoSafe Nasopharyngeal Airway ID Size 5.5mm 26 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-006U	NasoSafe Nasopharyngeal Airway ID Size 6.0mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N

114	038-95-065U	NasoSafe Nasopharyngeal Airway ID Size 6.5mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007U	NasoSafe Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-075U	NasoSafe Nasopharyngeal Airway ID Size 7.5mm 32 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-008U	NasoSafe Nasopharyngeal Airway ID Size 8.0mm 34 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-085U	NasoSafe Nasopharyngeal Airway ID Size 8.5mm 36 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-009U	NasoSafe Nasopharyngeal Airway ID Size 9.0mm 38 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N

Technical file: 114

114	038-95-004C	NasoClear Nasopharyngeal Airway ID Size 4.0mm 20 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-045C	NasoClear Nasopharyngeal Airway ID Size 4.5mm 22 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-005C	NasoClear Nasopharyngeal Airway ID Size 5.0mm 24 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-055C	NasoClear Nasopharyngeal Airway ID Size 5.5mm 26 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-006C	NasoClear Nasopharyngeal Airway ID Size 6.0mm 28Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-065C	NasoClear Nasopharyngeal Airway ID Size 6.5mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007C	NasoClear Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-075C	NasoClear Nasopharyngeal Airway ID Size 7.5mm 32 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-008C	NasoClear Nasopharyngeal Airway ID Size 8.0mm 34 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-085C	NasoClear Nasopharyngeal Airway ID Size 8.5mm 36 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-009C	NasoClear Nasopharyngeal Airway ID Size 9.0mm 38 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-004CU	NasoClear Nasopharyngeal Airway ID Size 4.0mm 20 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-045CU	NasoClear Nasopharyngeal Airway ID Size 4.5mm 22 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-005CU	NasoClear Nasopharyngeal Airway ID Size 5.0mm 24 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-055CU	NasoClear Nasopharyngeal Airway ID Size 5.5mm 26 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-006CU	NasoClear Nasopharyngeal Airway ID Size 6.0mm 28Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-065CU	NasoClear Nasopharyngeal Airway ID Size 6.5mm 28 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-007CU	NasoClear Nasopharyngeal Airway ID Size 7.0mm 30 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-075CU	NasoClear Nasopharyngeal Airway ID Size 7.5mm 32 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-008CU	NasoClear Nasopharyngeal Airway ID Size 8.0mm 34 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
114	038-95-085CU	NasoClear Nasopharyngeal Airway ID Size 8.5mm 36 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N

114	038-95-009CU	NasoClear Nasopharyngeal Airway ID Size 9.0mm 38 Fr	Class I Sterile (Rule 5)	42422	Nasopharyngeal airway, single-use	N
Technical File: 116						
Meatal Dilator – Standard Tip						
116	WCM08	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 08Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM10	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 10Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM12	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 12Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM14	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 14Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM16	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 16Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM18	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 18Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WCM01	WyCath Hydrophilic Meatal Dilator Standard Tip 12cm 12Ch 14Ch 16Ch (Mix Box)	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
Meatal Dilator – Tapered Tip						
116	WMT06	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 06Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT08	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 08Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT10	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 10Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT12	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 12Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT14	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 14Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT16	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 16Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT18	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 18Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMT20	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 20Ch	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
116	WMTM01	WyCath Hydrophilic Meatal Dilator Tapered Tip 12cm 12Ch 14Ch 16Ch (Mix Box)	Class I Sterile (Rule 5)	64677	Urethral dilator, single-use	N
Technical File: 117						
WyCath Plain Intermittent Catheter Female – Straight Tip						
117	03-51008	Plain Intermittent Catheter Female 18cm 8CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	03-51010	Plain Intermittent Catheter Female 18cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	03-51012	Plain Intermittent Catheter Female 18cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	03-51014	Plain Intermittent Catheter Female 18cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Male - Soft tip						
117	W2SM10	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Standard 40cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SM12	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Standard 40cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SM14	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Standard 40cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SM16	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Standard 40cm 16CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SM18	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Standard 40cm 18CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W4SM10	WyCath H2O Hydrophilic Intermittent Catheter 4 Eyelet Soft Tip Standard 40cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W4SM12	WyCath H2O Hydrophilic Intermittent Catheter 4 Eyelet Soft Tip Standard 40cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W4SM14	WyCath H2O Hydrophilic Intermittent Catheter 4 Eyelet Soft Tip Standard 40cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W4SM16	WyCath H2O Hydrophilic Intermittent Catheter 4 Eyelet Soft Tip Standard 40cm 16CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N

117	W4SM18	WyCath H2O Hydrophilic Intermittent Catheter 4 Eyelet Soft Tip Standard 40cm 18CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Male – Taper tip						
117	W2TAM10	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Standard 40cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAM12	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Standard 40cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAM14	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Standard 40cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAM16	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Standard 40cm 16CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAM18	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Standard 40cm 18CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Female – Soft Tip						
117	W2SF08	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Female 18cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SF10	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Female 18cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SF12	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Female 18cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SF14	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Female 18cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Female – Taper Tip						
117	W2TAF08	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Female 18cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAF10	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Female 18cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAF12	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Female 18cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAF14	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Female 18cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Female - Short						
117	W2SH08	WyCath H2O Hydrophilic Intermittent Catheter Short Female 11cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SH10	WyCath H2O Hydrophilic Intermittent Catheter Short Female 11cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SH12	WyCath H2O Hydrophilic Intermittent Catheter Short Female 11cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SH14	WyCath H2O Hydrophilic Intermittent Catheter Short Female 11cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Female						
117	W2F08	WyCath H2O Hydrophilic Intermittent Catheter Female 18cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2F10	WyCath H2O Hydrophilic Intermittent Catheter Female 18cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2F12	WyCath H2O Hydrophilic Intermittent Catheter Female 18cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2F14	WyCath H2O Hydrophilic Intermittent Catheter Female 18cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Paediatric - Soft tip						
117	W2SP08	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Paediatric 30cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2SP10	WyCath H2O Hydrophilic Intermittent Catheter Soft Tip Paediatric 30cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Paediatric - Tapered tip						
117	W2TAP06	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Paediatric 30cm 06CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N

117	W2TAP08	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Paediatric 30cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TAP10	WyCath H2O Hydrophilic Intermittent Catheter Tapered Tip Paediatric 30cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Paediatric						
117	W2P06	WyCath H2O Hydrophilic Intermittent Catheter Paediatric 30cm 06CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2P08	WyCath H2O Hydrophilic Intermittent Catheter Paediatric 30cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2P10	WyCath H2O Hydrophilic Intermittent Catheter Paediatric 30cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Paediatric– Tiemann Tip						
117	W2TP06	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Paediatric 30cm 06CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TP08	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Paediatric 30cm 08CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TP10	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Paediatric 30cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter Standard						
117	W2M10	WyCath H2O Hydrophilic Intermittent Catheter Standard 40cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2M12	WyCath H2O Hydrophilic Intermittent Catheter Standard 40cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2M14	WyCath H2O Hydrophilic Intermittent Catheter Standard 40cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2M16	WyCath H2O Hydrophilic Intermittent Catheter Standard 40cm 16CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath H2O Hydrophilic Intermittent Catheter – Tiemann Tip Standard						
117	W2TM10	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Standard 40cm 10CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TM12	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Standard 40cm 12CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TM14	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Standard 40cm 14CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TM16	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Standard 40cm 16CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
117	W2TM18	WyCath H2O Hydrophilic Intermittent Catheter Tiemann Tip Standard 40cm 18CH	Class I Sterile (Rule 5)	45603	Single-administration urethral drainage catheter	N
Technical File: 118						
118	00-0060	EZ-Flow Catheter Valve	Class I Sterile (Rule 1)	35375	Stopcock	N
118	00-0060U	EZ-Flow Catheter Valve	Class I Sterile (Rule 1)	35375	Stopcock	N
Technical File: 120a						
120a	040-283	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Kessel Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-284	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Kessel Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-331	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-331J	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-332	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Macintosh Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-332J	BritePro Solo With Pro Mac 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

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120a	040-340NU	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-340U	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-341J	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Miller Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-341U	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-342J	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Miller Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-342U	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-343J	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Miller Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-343U	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-344U	BritePro Solo Single-Use Fiber Optic Handle and Blade Miller 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-351U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-361U	BritePro Solo Single-Use Fiber Optic Handle and Blade Phillips 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-362U	BritePro Solo Single-Use Fiber Optic Handle and Blade Phillips 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-365	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Flexible McCoy Type Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-711HU	BritePro Handle Single-Use Fiber Optic and Blade Mac 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-711J	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-712HU	BritePro Handle Single-Use Fiber Optic and Blade Mac 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-713HU	BritePro Handle Single-Use Fiber Optic and Blade Mac 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-714HU	BritePro Handle Single-Use Fiber Optic and Blade Mac 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-720HU	BritePro Handle Single-Use Fiber Optic and Blade Miller 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-720NHU	BritePro Handle Single-Use Fiber Optic and Blade Miller 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-721HU	BritePro Handle Single-Use Fiber Optic and Blade Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-722HU	BritePro Handle Single-Use Fiber Optic and Blade Miller 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-723HU	BritePro Handle Single-Use Fiber Optic and Blade Miller 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-724HU	BritePro Handle Single-Use Fiber Optic and Blade Miller 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0210	BritePro Solo with Pro Side Light Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0210U	BritePro Solo Single-Use Fiber Optic Handle and Blade Side Light Mac 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0220	BritePro Solo with Pro Side Light Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120a	040-01-0220U	BritePro Solo Single-Use Fiber Optic Handle and Blade Side Light Mac 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0230	BritePro Solo with Pro Side Light Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0230U	BritePro Solo Single-Use Fiber Optic Handle and Blade Side Light Mac 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0231	BritePro Solo with Pro Side Light Mac Blade Size 3 Strong Curve	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0231U	BritePro Solo Single-Use Fiber Optic Handle and Blade Side Light Mac 3 Strong Curve	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0235	BritePro Solo with Pro Side Light Mac Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0630	BritePro Solo with Pro Polio Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0630U	BritePro Solo Single-Use Fiber Optic Handle and Blade Polio 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0640	BritePro Solo with Pro Polio Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0640U	BritePro Solo Single-Use Fiber Optic Handle and Blade Polio 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0730	BritePro Solo with Pro Kessel Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0730U	BritePro Solo Single-Use Fiber Optic Handle and Blade Kessel 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0740	BritePro Solo with Pro Kessel Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0740U	BritePro Solo Single-Use Fiber Optic Handle and Blade Kessel 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0810	BritePro Solo with Pro Seward Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0810U	BritePro Solo Single-Use Fiber Optic Handle and Blade Seward 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0820	BritePro Solo with Pro Seward Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0820U	BritePro Solo Single-Use Fiber Optic Handle and Blade Seward 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0110	BritePro Solo Mini with Pro Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0110U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0120	BritePro Solo Mini with Pro Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0120U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0130	BritePro Solo Mini with Pro Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0130U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0131	BritePro Solo Mini + BriteBlade Pro Mac Blade Size 3 Strong Curve	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0131U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 3 Strong Curve	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0135	BritePro Solo Mini + BriteBlade Pro Mac Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120a	040-02-0135U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0140	BritePro Solo Mini with Pro Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0140U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Mac 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0400	BritePro Solo Mini with Pro Miller Blade Size 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0400U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0401	BritePro Solo Mini with Pro Miller Blade Size 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0401U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0410	BritePro Solo Mini with Pro Miller Blade Size Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0410U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0415	BritePro Solo Mini with Pro Miller Blade Size 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0415U	BritePro Solo Mini with Pro Miller Blade Size 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0420	BritePro Solo Mini with Pro Miller Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0420U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0430	BritePro Solo Mini with Pro Miller Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0430U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0440	BritePro Solo Mini with Pro Miller Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0440U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Miller 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0510U	BritePro Solo Mini with Pro Side Light Miller Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0630U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Polio 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0640U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Polio 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0730U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Kessel 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0740U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Kessel 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0810U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Seward 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0820U	BritePro Solo Single-Use Fiber Optic Mini Handle and Blade Seward 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0130	BritePro Solo Single Use Fibre Optic Stubby Laryngoscope Handle and Macintosh Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0130U	BritePro Solo Single Use Fiber Optic Stubby Laryngoscope Handle and Macintosh Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0140	BritePro Solo Single Use Fibre Optic Stubby Laryngoscope Handle and Macintosh Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120a	040-03-0140U	BritePro Solo Single Use Fiber Optic Stubby Laryngoscope Handle and Macintosh Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0630	BritePro Solo Single Use Fibre Optic Stubby Laryngoscope Handle and Polio Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0630U	BritePro Solo Single Use Fiber Optic Stubby Laryngoscope Handle and Polio Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0640	BritePro Solo Single Use Fibre Optic Stubby Laryngoscope Handle and Polio Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-03-0640U	BritePro Solo Single Use Fiber Optic Stubby Laryngoscope Handle and Polio Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0240	BritePro Solo with Pro Side Light Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0500	BritePro Solo with Pro Side Light Miller Blade Size 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0501	BritePro Solo with Pro Side Light Miller Blade Size 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0510	BritePro Solo with Pro Side Light Miller Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0515	BritePro Solo with Pro Side Light Miller Blade Size 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0520	BritePro Solo with Pro Side Light Miller Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0530	BritePro Solo with Pro Side Light Miller Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-0540	BritePro Solo with Pro Side Light Miller Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-01-1110	BritePro Solo with Pro Robertshaw Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0210	BritePro Solo Mini with Pro Side Light Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0220	BritePro Solo Mini with Pro Side Light Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0230	BritePro Solo Mini with Pro Side Light Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0231	BritePro Solo Mini with Pro Side Light Mac Blade Size 3 Strong Curve	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0235	BritePro Solo Mini with Pro Side Light Mac Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0240	BritePro Solo Mini with Pro Side Light Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0310	BritePro Solo Mini with Pro Flexi Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0320	BritePro Solo Mini with Pro Flexi Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0330	BritePro Solo Mini with Pro Flexi Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-02-0340	BritePro Solo Mini with Pro Flexi Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-290	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Robertshaw Blade Size Blade Size 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-291	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Robertshaw Blade Size Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120a	040-363	BritePro Solo Single Use Fibre Optic Laryngoscope Handle and Phillips Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120a	040-364	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Phillips Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
Technical file:120a						
120a	040-03-0000	BritePro Solo Single Use Fibre Optic Stubby Handle	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-03-0000U	BritePro Solo Stubby Single-Use Fiber Optic Laryngoscope Handle	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-309	BritePro Solo Single Use Fibre Optic Mini Laryngoscope Handle	Class I Sterile (Rule 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-309U	BritePro Solo Mini Single-Use Fiber Optic Laryngoscope Handle	Class I Sterile (Rule 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-310	BritePro Solo Single Use Fibre Optic Laryngoscope Handle	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-310J	BritePro Solo Single Use Fibre Optic Laryngoscope Handle	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-310U	BritePro Solo Single-Use Fiber Optic Laryngoscope Handle	Class I Sterile (Rule 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-791	BritePro Fibre Optic Single Use Laryngoscope Handle	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
120a	040-791U	BritePro Handle Single-Use Fiber Optic	Class I Sterile (Rule 5 & 12)	47806	Laryngoscope Handle, Single Use	Y
Technical File:120a						
120a	040-00-0121	BriteBlade Pro Single Use Fibre Optic Macintosh Strong Curve Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0121U	BriteBlade Pro Single Use Fiber Optic Macintosh Strong Curve Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-04000	BriteBlade Pro Fibre Optic Single Use Laryngoscope Miller Blade Size 000	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-04000U	BriteBlade Pro Single-Use Fiber Optic Miller 000	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0630	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0630U	BriteBlade Pro Single-Use Fiber Optic Polio 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0640	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0640U	BriteBlade Pro Single-Use Fiber Optic Polio 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0730	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0730U	BriteBlade Pro Single-Use Fiber Optic Kessel 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0740	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0740U	BriteBlade Pro Single-Use Fiber Optic Kessel 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0810	BriteBlade Pro Single Use Fibre Optic Seward Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0810U	BriteBlade Pro Single-Use Fiber Optic Seward 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0820	BriteBlade Pro Single Use Fibre Optic Seward Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0820U	BriteBlade Pro Single-Use Fiber Optic Seward 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

120a	040-00-1101	BriteBlade Pro Single Use Fibre Optic Robertshaw Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1101U	BriteBlade Pro Single-Use Fiber Optic Robertshaw 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1110	BriteBlade Pro Single Use Fibre Optic Robertshaw Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1110U	BriteBlade Pro Single-Use Fiber Optic Robertshaw 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1210	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1210U	BriteBlade Pro Single-Use Fiber Optic Wis-Hipple 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1215	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1215U	BriteBlade Pro Single-Use Fiber Optic Wis-Hipple 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1220	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1220U	BriteBlade Pro Single-Use Fiber Optic Wis-Hipple 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1230	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1230U	BriteBlade Pro Single-Use Fiber Optic Wis-Hipple 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1240	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1240U	BriteBlade Pro Single-Use Fiber Optic Wis-Hipple 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1800	BriteBlade Pro Single Use Fibre Optic Centreline Miller Blade Size 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1800U	BriteBlade Pro Single Use Fiber Optic Centerline Miller 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1801	BriteBlade Pro Single Use Fibre Optic Centreline Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1801U	BriteBlade Pro Single Use Fiber Optic Centerline Miller 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1810	BriteBlade Pro Single Use Fibre Optic Centreline Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1810U	BriteBlade Pro Single Use Fiber Optic Centerline Miller 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1820	BriteBlade Pro Single Use Fibre Optic Centreline Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1820U	BriteBlade Pro Single Use Fiber Optic Centerline Miller 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1830	BriteBlade Pro Single Use Fibre Optic Centerline Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1830U	BriteBlade Pro Single Use Fiber Optic Centerline Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1840	BriteBlade Pro Single Use Fibre Optic Centerline Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-1840U	BriteBlade Pro Single Use Fiber Optic Centerline Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
Single Use Fibre Optic Blade						
120a	040-673	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

120a	040-674	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-683	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-684	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-711	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-711U	BriteBlade Pro Single-Use Fiber Optic Mac 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-712	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-712J	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-712U	BriteBlade Pro Single-Use Fiber Optic Mac 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-713	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-713J	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-713U	BriteBlade Pro Single-Use Fiber Optic Mac 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-714	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-714J	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-714U	BriteBlade Pro Single-Use Fiber Optic Mac 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-715	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-715U	BriteBlade Pro Single-Use Fiber Optic Mac 3.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-716	BriteBlade Pro Single Use Fibre Optic Macintosh Strong Curve Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-716U	BriteBlade Pro Single-Use Fiber Optic Mac 3 Strong Curve	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-717	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720N	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720J	Briteblade Pro S/Use Fibre Optic Miller Size 0 Blade	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720NJ	Briteblade Pro S/Use Fibre Optic Miller Size 00 Blade	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720NU	BriteBlade Pro Single-Use Fiber Optic Miller 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-720U	BriteBlade Pro Single-Use Fiber Optic Miller 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-721	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-721J	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-721U	BriteBlade Pro Single-Use Fiber Optic Miller 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

120a	040-722	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-722J	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-722U	BriteBlade Pro Single-Use Fiber Optic Miller 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-723	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-723U	BriteBlade Pro Single-Use Fiber Optic Miller 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-724	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-724U	BriteBlade Pro Single-Use Fiber Optic Miller 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-741	BriteBlade Pro Fibre Optic Single Use Laryngoscope Phillips Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-741U	BriteBlade Pro Single-Use Fiber Optic Phillips 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-742	BriteBlade Pro Fibre Optic Single Use Laryngoscope Phillips Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-742U	BriteBlade Pro Single-Use Fiber Optic Phillips 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-751	BriteBlade Pro Fibre Optic Single Use Laryngoscope Macintosh Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-752	BriteBlade Pro Fibre Optic Single Use Laryngoscope Macintosh Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-753	BriteBlade Pro Fibre Optic Single Use Laryngoscope Macintosh Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-754	BriteBlade Pro Fibre Optic Single Use Laryngoscope Macintosh Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-760NU	BriteBlade Pro Evo Single-Use Fiber Optic Miller 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-760U	BriteBlade Pro Evo Single-Use Fiber Optic Miller 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-761	BriteBlade Pro Fiber Optic Single Use Laryngoscope Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-762	BriteBlade Pro Fibre Optic Single Use Laryngoscope Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-763	BriteBlade Pro Fibre Optic Single Use Laryngoscope Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-764	BriteBlade Pro Fibre Optic Single Use Laryngoscope Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-771	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Macintosh Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-772	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Macintosh Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-773	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Macintosh Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-774	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Macintosh Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-775	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-776	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

120a	040-777	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-778	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-779	BritePro Fibre Optic Single Use Laryngoscope Handle and Pro Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0210	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0210U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0220	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0220U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0230	BriteBlade Pro Single Use Fibre Optic Side Light Macintosh Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0230U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0231	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 3 Strong Curve	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0231U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 3 Strong Curve	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0235	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 3.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0235U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 3.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0240	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0240U	BriteBlade Pro Single Use Fibre Optic Side Light Mac Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0405U	BriteBlade Pro Single-Use Fiber Optic Miller 000	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0415	BriteBlade Pro Fibre Optic Single Use Laryngoscope Miller Blade Size 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0415U	BriteBlade Pro Fibre Optic S/Use Laryngoscope Miller Blade 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0421	BriteBlade Pro Single Use Fibre Optic Curved Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0421U	BriteBlade Pro S/Use Fibre Optic Curved Miller Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0500	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0500U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 00	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0501	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0501U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 0	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0510	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0510U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 1	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0515	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

120a	040-00-0515U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 1.5	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0520	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0520U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 2	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0530	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0530U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 3	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0540	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N
120a	040-00-0540U	BriteBlade Pro Single Use Fibre Optic Side Light Miller Blade Size 4	Class I Sterile (Rule 5)	46828	Laryngoscope Blade, Single Use	N

Technical File: 120c

BritePro Omni – Standard handle

120c	040-04-0110	Omni Integrated Single Use Laryngoscope Handle and Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0110U	Omni Integrated Single Use Laryngoscope Handle and Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0120	Omni Integrated Single Use Laryngoscope Handle and Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0120U	BritePro Omni Single-Use Laryngoscope Handle With Mac 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0130	Omni Integrated Single Use Laryngoscope Handle and Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0130U	BritePro Omni Single-Use Laryngoscope Handle With Mac 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0135U	Omni Integrated Single Use Laryngoscope Handle Mac Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0140	Omni Integrated Single Use Laryngoscope Handle and Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0140U	BritePro Omni Single-Use Laryngoscope Handle With Mac 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0400U	BritePro Omni Single-Use Laryngoscope Handle With Miller 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0401U	BritePro Omni Single-Use Laryngoscope Handle With Miller 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0410U	BritePro Omni Single-Use Laryngoscope Handle With Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0415U	Omni Integrated Single Use Laryngoscope Handle Miller Blade Size 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0420	BritePro Omni Single Use All-in-One Laryngoscope Handle and Miller Laryngoscope Blade Size 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0420U	BritePro Omni Single-Use Laryngoscope Handle With Miller 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0430	BritePro Omni Single Use All-in-One Laryngoscope Handle and Miller Laryngoscope Blade Size 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0430U	BritePro Omni Single-Use Laryngoscope Handle With Miller 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120c	040-04-0440	BritePro Omni Single Use All-in-One Laryngoscope Handle and Miller Laryngoscope Blade Size 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0440U	BritePro Omni Single-Use Laryngoscope Handle With Miller 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2010U	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2020U	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2030U	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2040U	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-0135	Omni Integrated Single Use Laryngoscope Handle Mac Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2010	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2015	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2015U	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2020	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 2	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2030	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 3	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-04-2040	BritePro Omni Single-Use Laryngoscope Handle With Miller Ultra 4	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
BritePro Omni – Mini Handle						
120c	040-06-0110	BritePro Omni Single Use All-in-One Mini Laryngoscope Handle and Macintosh Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0110U	BritePro Omni Single Use All-in-One Mini Laryngoscope Handle and Macintosh Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0400	BritePro Omni Single Use All-in-One Mini Laryngoscope Handle and Miller Blade Size 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0400U	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0401	BritePro Omni Single Use All-in-One Mini Laryngoscope Handle and Miller Blade Size 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0401U	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0410	BritePro Omni Single Use All-in-One Mini Laryngoscope Handle and Miller Blade Size 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-0410U	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2000	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2000U	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 00	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2001	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2001U	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 0	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2010	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2010U	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 1	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y

120c	040-06-2015	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-2015U	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 1.5	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-20000	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 000	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
120c	040-06-20000U	BritePro Omni Single-Use Laryngoscope Mini Handle With Miller Ultra 000	Class I Sterile (Rule 5 & 12)	62918	Rigid intubation laryngoscope, single-use	Y
Technical File: 120e						
120e	040-08-0110	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0110U	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 1	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0120	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0120U	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0130	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0130U	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0140	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0140U	ProVu Single Use Video Laryngoscope Handle with Mac Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0420	ProVu Single Use Video Laryngoscope Handle with Miller Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-0420U	ProVu Single Use Video Laryngoscope Handle with Miller Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-1930	ProVu Single Use Video Laryngoscope Handle with Channel Hyper Angulated Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-1930U	ProVu Single Use Video Laryngoscope Handle with Channel Hyper Angulated Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-1940	ProVu Single Use Video Laryngoscope Handle with Channel Hyper Angulated Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-1940U	ProVu Single Use Video Laryngoscope Handle with Channel Hyper Angulated Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2110	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 1	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2110U	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 1	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2120	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y

120e	040-08-2120U	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 2	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2130	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2130U	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 3	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2135	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2135U	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 3.5	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2140	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-08-2140U	ProVu Single Use Video Laryngoscope Handle with Hyper Angulated Blade Size 4	Class I Sterile (Rule 5 & 12)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0110	ProVu Single Use Mini Video Laryngoscope Handle with Mac Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0110U	ProVu Single Use Mini Video Laryngoscope Handle with Mac Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0120	ProVu Single Use Mini Video Laryngoscope Handle with Mac Blade Size 2	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0120U	ProVu Single Use Mini Video Laryngoscope Handle with Mac Blade Size 2	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-2110	ProVu Single Use Mini Video Laryngoscope Handle with Hyper Angulated Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-2110U	ProVu Single Use Mini Video Laryngoscope Handle with Hyper Angulated Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-2120	ProVu Single Use Mini Video Laryngoscope Handle with Hyper Angulated Blade Size 2	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-2120U	ProVu Single Use Mini Video Laryngoscope Handle with Hyper Angulated Blade Size 2	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0410U	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 00	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0410	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 00	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0400	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 0	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0400U	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 0	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0401	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation laryngoscope kit	Y
120e	040-09-0401U	ProVu Mini Video Laryngoscope Handle with Miller Blade Size 1	Class I Sterile (Rule 5)	62763	Video intubation	Y

ANNEX A – INTENDED PURPOSE

TECHNICAL FILE/ TF:003
Suction Tubing (Sterile) - A length of flexible non-invasive tube, typically made of synthetic polymer material(s), intended to connect a suction catheter to a collection bottle/canister, a collection canister/bottle to a regulator/suction pump, or to connect a series of collection bottles/canisters to increase the total capacity within a suction system. The device may be provided in rolls from which required lengths are cut, or in predetermined lengths with built-in connectors. This is a single-use device.
TECHNICAL FILE/ TF:019a
Leg Bags (Sterile) - A sterile flexible plastic pouch designed to connect to a urinary catheter or a urinary condom catheter and to be strapped to the leg of a patient to collect discharged urine; it is designed with an opening for urine drainage. Also known as a leg bag, it is worn on the body to facilitate patient mobility. This is a single-use device.
TECHNICAL FILE/ TF:019b
Drainable Bags (Sterile) - A sterile flexible plastic pouch designed to connect to a urinary catheter or a urinary condom catheter to collect discharged urine from a patient; it is designed with an opening for urine drainage. The device is not directly attached to the patient. This is a single-use device. Non-Drainable Bags (Sterile) - A sterile flexible plastic pouch designed to connect to a urinary catheter to collect discharged urine from a patient; it is not designed with an opening for urine drainage. The device is not directly attached to the patient and is disposed of when full. This is a single-use device.
TECHNICAL FILE/ TF:027
Vaginal Speculum (Sterile) - A hand-held manual instrument intended to dilate the vagina after insertion, typically for visual examination of the vaginal canal and cervix and/or to perform a gynaecological procedure. It typically consists of two long blades, joined at a handle at one end, that are inserted into the vagina in a horizontal position and then opened to form an angle, or it is a soft-material device inflated after insertion that allows viewing and access through a central channel. It is typically made entirely of plastic materials or has removable blades made of plastic. This is a single-use device.
TECHNICAL FILE/ TF:028
CO2 Absorbents (Sterile) - An absorbent material (e.g., granules of treated soda lime) intended to be placed into a reusable carbon dioxide absorber to remove carbon dioxide (CO ₂) from the exhaled gases in a patient breathing circuit by chemical reaction. It is typically available in large plastic containers [e.g., 5 kilogrammes (Kg) by weight] and poured into clean, reusable absorbers. The absorbent is typically manufactured to change colour during its use (e.g., from white to violet, pink to white, or green to violet) to indicate need for replacement. This is a single-use device.
TECHNICAL FILE/ TF:030a
Guedel Airways (Sterile, Single Use) - A curved metal or plastic tube inserted through the mouth to facilitate airway patency for gas exchange or suctioning. The device prevents the tongue from obstructing airflow. This is a single-use device.
TECHNICAL FILE/ TF:030c
Williams Airway- Oropharyngeal Airway (Sterile, Single Use) - A curved metal or plastic tube inserted through the mouth to facilitate airway patency for gas exchange or suctioning. The device prevents the tongue from obstructing airflow. This is a single-use device.
TECHNICAL FILE/ TF:040
Urimeter- Urine Collection Device (Sterile, Single Use) - A non-electrical device that is used to measure the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder. This device is a single-use device.
TECHNICAL FILE/ TF:056c
Anaesthesia Components (Sterile and Non-Sterile) - A non-sterile device intended to connect a breathing circuit breathing tube to an endotracheal (ET) tube, anaesthesia face mask, or other non-sampling breathing circuit component. It is constructed with standardized connecting dimensions and may be designed to connect breathing tubes from paediatric to adult sizes. It is typically made of plastic materials and can have a straight or elbow-shaped design (excluding Y-piece connectors). Some designs may allow for partial rotation at the point of connection (a swivel) and may include a suction port or gas sampling port. This is a single-use device.
TECHNICAL FILE/ TF:108
Bougies- Tracheal Intubation Aid (Sterile, Single Use) - A sterile, long, stiffening wire/rod designed for insertion within the lumen of an artificial airway tube (e.g., endotracheal tube, bronchial tube) to stiffen and/or maintain the shape of the tube to facilitate introduction (intubation). It is designed to be slightly shorter than the tube to avoid damage to the airway during passage and is withdrawn after intubation has been completed. This is a single-use device.
TECHNICAL FILE/ TF:109
Stylet- Tracheal Intubation Aid (Sterile, Single Use) - A sterile, long, stiffening wire/rod designed for insertion within the lumen of an artificial airway tube (e.g., endotracheal tube, bronchial tube) to stiffen and/or maintain the shape of

the tube to facilitate introduction (intubation). It is designed to be slightly shorter than the tube to avoid damage to the airway during passage and is withdrawn after intubation has been completed. This is a single-use device.

TECHNICAL FILE/ TF:114

Nasopharyngeal Airway (Sterile, Single Use)- A rubber or plastic tube that extends into the pharynx from either naris to maintain airway patency. The proximal end of the device may have an integral 22 mm connector for oxygen delivery. This is a single-use device.

TECHNICAL FILE/ TF:116

Meatal Dilators (Sterile, Single Use)- Meatal Dilators are intended for use on adult and paediatric individuals who have strictures/narrowing of the meatus, which include meatal stenosis and meatal strictures near the opening of the urethra. Strictures/narrowing of the meatus can lead to a poor stream of urine or spraying when passing urine, difficulty in passing urine and having to strain or taking a long time to empty the bladder. Meatal Dilators are intended to dilate the opening of the urethra to allow the patient to pass urine naturally or subsequently use a catheter. Meatal Dilators may be used in hospital and home environments. The device is intended to be used by trained users. Meatal Dilators are to be used for a maximum of 5 minutes and are single use. Once the device is removed it should be disposed of. Flexicare's Meatal Dilators are intended for use in adult and paediatric individuals who have strictures or narrowing of the meatus or urethra.

TECHNICAL FILE/ TF:117

Classic - Intermittent Urinary Catheters (Sterile)- A sterile, flexible tube intended to be inserted one-time through the urethra to the urinary bladder, by the patient/user or a healthcare provider, to provide urine drainage, typically for an individual who is physiologically incapable of voiding. It is typically made of polyvinyl chloride (PVC) and may be coated with a lubricating substance (e.g., acquires a smooth and mucous surface when brought in contact with water). The distal end can have various tip designs [e.g., open-ended, rounded with a side-hole(s)], and the proximal end typically connects to a urine collection container. This is a single-use device.

TECHNICAL FILE/ TF:118

Urinary Catheter Valve (Sterile)- A general-purpose valve that is used to regulate the direction of a liquid or a gas flow. It is typically constructed of a durable material, e.g., plastic and/or metal, and may be used for a variety of general-purpose uses. This is a single-use device.

TECHNICAL FILE/ TF:120a

Laryngoscope (Sterile, Single Use)- A hand-held disposable device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. It has a handle containing batteries to power its light (a small built-in light bulb or fibreoptic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/interchanged or integral. Some types are magnetic resonance imaging (MRI) compatible. This is a single-use device.

Laryngoscope Handle (Sterile, Single Use)- A hand-held disposable device intended to be connected to a laryngoscope blade to enable a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. The device contains batteries to power its light (a small LED fibreoptic light). This is a single-use device.

Laryngoscope Blades (Sterile, Single Use)- The segment of a laryngoscope (i.e., rigid intubation type) intended to be inserted into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. It is connected to the laryngoscope handle and illumination of the airway is provided by a small built-in light bulb or a fibreoptic light. This device may be curved or straight and of various designs and lengths; it may be hinged/interchanged with the handle. This is a single-use device.

TECHNICAL FILE/ TF:120c

Laryngoscope (Sterile, Single Use)- A hand-held disposable device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. Its Blade contains batteries to power its light (a small built-in LED) for airway illumination, and a curved or straight blade of various designs and lengths. This is a single-use device.

TECHNICAL FILE/ TF:120e

Video Laryngoscope (Sterile, Single Use)- A hand-held disposable device intended to be used by anaesthesia/emergency service personnel to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. It has a handle containing batteries to power its light (a small built-in light bulb or fibreoptic light) for airway illumination, and a curved or straight blade of various designs and lengths that can be hinged/interchanged or integral. Some types are magnetic resonance imaging (MRI) compatible. This is a single-use device.

DOC-000002-25 Declaration of Conformity for Class Is+m Devices (final)

Final Audit Report

2024-08-19

Created:	2024-08-19
By:	Lys Izere (lys.izere@flexicare.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAUJOpm0001smnuTYDM_mph3XgeelcX5vd

"DOC-000002-25 Declaration of Conformity for Class Is+m Devices (final)" History

-  Document created by Lys Izere (lys.izere@flexicare.com)
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-  Document emailed to gurge phull (gurjeet.phull@flexicare.com) for signature
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-  Email viewed by gurge phull (gurjeet.phull@flexicare.com)
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-  Signer gurge phull (gurjeet.phull@flexicare.com) entered name at signing as Dr. Gurge Phull
2024-08-19 - 5:42:42 PM GMT
-  Document e-signed by Dr. Gurge Phull (gurjeet.phull@flexicare.com)
Signature Date: 2024-08-19 - 5:42:44 PM GMT - Time Source: server
-  Agreement completed.
2024-08-19 - 5:42:44 PM GMT



Flexicare Medical Limited

Cwm Cynon Business Park,
Mountain Ash
CF45 4ER
United Kingdom- UK

22/04/2024

Confirmation Letter Reference: CLNB1639 - GBPC 05884

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance 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:

Flexicare Medical Limited

Cwm Cynon Business Park,
Mountain Ash
CF45 4ER
United Kingdom- UK
SRN: GB-MF-000034163

Authorised Representative:

Flexicare Deutschland GmbH
Ohlenhohnstrasse 34,
53819 Neunkirchen-Seelscheid,
Germany
SRN: DE-AR-000029825

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the

SGS Belgium NV

Certification and Business Enhancement Registered Office: Noorderlaan 87 BE-2030 Antwerpen t +32 (0)3 545 48 48 f +32 (0)3 545 48 49
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RPR Antwerpen VAT BE 0404 882 750 Belfius 550-3560000-93

devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th 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:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 NB1639,



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

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Suction Tubing (Sterile) 505578870000302FH	Class Is	Suction Tubing	N/A	GB19/964678; NB1639
Drainable Bags (Sterile) 5055788700001907GY	Class Is	Suction Tubing	N/A	GB19/964678; NB1639
Leg Bags (Sterile) 5055788700001906GW	Class Is	Leg Bags (Sterile)	N/A	GB19/964678; NB1639
Non-Drainable Bags (Sterile) 5055788700001908H2	Class Is	Non-Drainable Bags (Sterile)	N/A	GB19/964678; NB1639
Oropharyngeal Airways (Sterile Guedel) 5055788700003002FP	Class Is	Oropharyngeal Airways (Sterile Guedel)	N/A	GB19/964678; NB1639
Oropharyngeal Airways (Williams) 5055788700003004FT	Class Is	Oropharyngeal Airways (Williams)	N/A	GB19/964678; NB1639
Breathing System Components and Accessories (Sterile Safety Caps) 5055788700056C04LZ	Class Is	Breathing System Components and Accessories (Sterile Safety Caps)	N/A	GB19/964678; NB1639
Bougies and Stylets (Bougies) 5055788700010801GK	Class Is	Bougies	N/A	GB19/964678; NB1639
Bougies and Stylets (Stylets) 5055788700010802GM	Class Is	Bougies	N/A	GB19/964678; NB1639
Nasopharyngeal Airways (Sterile) 5055788700011401G6	Class Is	Nasopharyngeal Airways	N/A	GB19/964678; NB1639
Meatal Dilators (Sterile) 5055788700011601GG	Class Is	Meatal Dilators (Sterile)	N/A	GB19/964678; NB1639

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Intermittent and Short Term Use Catheters (Hydrophillic) 5055788700011701GM	Class Is	Intermittent and Short Term Use Catheters (Hydrophillic)	N/A	GB19/964678; NB1639
Intermittent and Short Term Use Catheters (Lubricated) 5055788700011702GP	Class Is	Intermittent and Short Term Use Catheters (Lubricated)	N/A	GB19/964678; NB1639
Intermittent and Short Term Use Catheters (Plain) 5055788700011703GR	Class Is	Intermittent and Short Term Use Catheters (Plain)	N/A	GB19/964678; NB1639
EZ-Flow Catheter Valves 5055788700001909H4	Class Is	EZ-Flow Catheter Valves	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Blade, Sterile 5055788700120A02JM	Class Is	BritePro Solo Handle and Fibre Optic Blades (Blade, Sterile)	N/A	GB19/964678; NB1639
Video Laryngoscope Handle with Blade 5055788700120E01K7	Class Is	Laryngoscope Blade	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Handle, Sterile) 5055788700120A03JP	Class Is	BritePro Solo Handle and Fibre Optic Blades (Handle, Sterile)	N/A	GB19/964678; NB1639
BritePro Solo Handle and Fibre Optic Blades (Laryngoscope, Sterile) 5055788700120A06JV	Class Is	BritePro Solo Handle and Fibre Optic Blades (Laryngoscope, Sterile)	N/A	GB19/964678; NB1639
BritePro Omni (Sterile) 5055788700120C02JX	Class Is	BritePro Omni (Sterile)	N/A	GB19/964678; NB1639

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Urimeter 5055788700004001FU	Class Is	Urine drainage bags	N/A	GB19/964678; NB1639
Manual Resuscitator Bags	Class IIa	Manual Resuscitator Bags	N/A	GB19/964677; NB1639
CO2 Absorbents	Class IIa	CO2 Absorbents	N/A	GB19/964677; NB1639
Nasal Cannulas	Class IIa	Nasal Cannulas	N/A	GB19/964677; NB1639
Oxygen Masks	Class IIa	Oxygen Masks	N/A	GB19/964677; NB1639
Oxygen Therapy Accessories	Class IIa	Oxygen Therapy Accessories	N/A	GB19/964677; NB1639
Resuscitation Circuits	Class IIa	Resuscitation Circuits	N/A	GB19/964677; NB1639
Resuscitation Units	Class IIa	Resuscitation Units	N/A	GB19/964677; NB1639
Filter – Electrostatic	Class IIa	Filter – Electrostatic	N/A	GB19/964677; NB1639
Filters – Mechanical	Class IIa	Filters – Mechanical	N/A	GB19/964677; NB1639
Nebulisers	Class IIa	Nebulisers	N/A	GB19/964677; NB1639
Anaesthesia Circuits	Class IIa	Anaesthesia Circuits	N/A	GB19/964677; NB1639
Ventilator Circuits	Class IIa	Ventilator Circuits	N/A	GB19/964677; NB1639
Breathing Systems Components and Accessories	Class IIa	Breathing Systems Components and Accessories	N/A	GB19/964677; NB1639

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Humidification Circuits	Class IIa	Humidification Circuits	N/A	GB19/964677; NB1639
Laryngeal Mask Airways	Class IIa	Laryngeal Mask Airways	N/A	GB19/964677; NB1639
Heat and Moisture Exchange Filters (HMEFs)	Class IIa	Heat and Moisture Exchange Filters (HMEFs)	N/A	GB19/964677; NB1639
Heat and Moisture Exchangers (HMEs)	Class IIa	Heat and Moisture Exchangers (HMEs)	N/A	GB19/964677; NB1639
Video Stylets	Class IIa	Video Stylets	N/A	GB19/964677; NB1639
Intermittent and Short Term Use Catheters	Class IIa	Short term Use Urinary Catheter	N/A	GB19/964677; NB1639
Suction Catheters	Class IIa	Suction Catheters	N/A	GB19/964677; NB1639
Closed Suction Catheters	Class IIa	Closed Suction Catheters	N/A	GB19/964677; NB1639
Endotracheal Tubes	Class IIa	Endotracheal Tubes	N/A	GB19/964677; NB1639
Endoscopy Bite Block	Class IIa	Endoscopy Bite Block with O2 delivery and CO2 monitoring	N/A	GB19/964677; NB1639
Suction Yankauers	Class IIa	Suction Yankauers	N/A	GB19/964677; NB1639
Pocket Resuscitation First Aid Masks	Class IIa	Pocket Resuscitation First Aid Masks	N/A	GB19/964677; NB1639

Device name or Basic UDI-DI	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	MDD Device name (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Anesthesia Facemasks	Class IIa	Anesthesia Facemasks	N/A	GB19/964677; NB1639
Sterile Stoma Plugs	Class IIa	Sterile Stoma Plugs	N/A	GB19/964677; NB1639
Altera Breathing Circuits	Class IIa	Altera Breathing Circuits	N/A	GB19/964677; NB1639
Silicone Foley Catheters FL9000	Class IIb	Silicone Foley Catheters FL9000	N/A	GB19/964677; NB1639
FL9000 (Adapter Leads)	Class IIb	FL9000 (Adapter Leads)	N/A	GB19/964677; NB1639
FL9000 (Temperature Probes)	Class IIb	FL9000 (Temperature Probes)	N/A	GB19/964677; NB1639
FL10000	Class IIb	FL10000	N/A	GB19/964677; NB1639
FL10000 (Adapter Leads)	Class IIb	FL10000 (Adapter Leads)	N/A	GB19/964677; NB1639
FL10000 (Temperature Probes)	Class IIb	FL10000 (Temperature Probes)	N/A	GB19/964677; NB1639
Booster Heater	Class IIb	Booster Heater – Respiratory Humidifier	N/A	GB19/964677; NB1639

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Suction Tubing (Non-Sterile) 5055788700000301FF	Class I	N/A	MDD self-certified
Drainage Bags (Stands) 5055788700001901GL	Class I	N/A	MDD self-certified
Drainage Bags (Securing Devices) 5055788700001902GN	Class I	N/A	MDD self-certified
Leg Bags (Non-Sterile) 5055788700001903GQ	Class I	N/A	MDD self-certified
2L Bags (Drainable) Neonatal 5055788700001904GS	Class I	N/A	MDD self-certified
2l Bags (Non-Drainable) 5055788700001905GU	Class I	N/A	MDD self-certified
Oropharyngeal Airways - Guedel Airways (Non-Sterile, Single Use) 5055788700030A01JH	Class I	N/A	MDD self-certified
Oropharyngeal Airways - Berman Airways (Non-Sterile, Single Use) 5055788700030B01JN	Class I	N/A	MDD self-certified
Jaw Opener (Non-Sterile, Single Use) 5055788700031A01JQ	Class I	N/A	MDD self-certified
ET Tube Holder (Non-Sterile, Single Use) 5055788700031B01JV	Class I	N/A	MDD self-certified
Magill Forceps (Non-Sterile, Single Use)	Class I	N/A	MDD self-certified

5055788700031C01K2			
Resuscitation Units (Mounting Brackets) 5055788700033B01KB	Class I	N/A	MDD self-certified
Filters - Electrostatic (Pulmonary Function Test Filter Nose Clip) 5055788700041B05KG	Class I	N/A	MDD self-certified
Ventilator Circuits (Headstrap for CPAP Mask) 5055788700056B01LN	Class I	N/A	MDD self-certified
Breathing System Components and Accessories (Non- Sterile Safety Caps) 5055788700056C33GS	Class I	N/A	MDD self-certified
Enema and Douche Devices (Non-Sterile, Single Use) 5055788700082A01LN	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Fibre Optic, Blade, Non- Sterile) 5055788700011501GB	Class I	N/A	MDD self-certified
Single Use Blades - Fiber Optic (Non- Sterile, Single Use) 5055788700120A01JK	Class I	N/A	MDD self-certified
LarySeal Cuff Inflator (Non-Sterile, Reusable) 5055788700120B01JQ	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Conventional, Blade) 5055788700120A07JX	Class I	N/A	MDD self-certified
Single Use Laryngoscopes (Fibre Optic, Laryngoscope, Non-Sterile) 5055788700120A05JT	Class I	N/A	MDD self-certified

Single Use Laryngoscopes (Fibre Optic, Handle, Non- Sterile) 5055788700120A04JR	Class I	N/A	MDD self-certified
BritePro Omni (Non- Sterile) 5055788700120C01JV	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Laryngoscope) 5055788700120D03K6	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Blade) 5055788700120D02K4	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Conventional, Handle) 5055788700120D01K2	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Laryngoscope) 5055788700120D06KC	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Blade) 5055788700120D05KA	Class I	N/A	MDD self-certified
Reusable Laryngoscopes (Fibre Optic, Handle) 5055788700120D04K8	Class I	N/A	MDD self-certified
NS SU Laryngoscopes (Non-Sterile, Single Use) 5055788700120F01KC	Class I	N/A	MDD self-certified
Endoscopy Bite Block (EasyGuard) 5055788700012401GD	Class I	N/A	MDD self-certified

FL9000 (Adapter Leads) 5055788700132A03KG	Class I	N/A	MDD self-certified
FL9000 (Accessories) 5055788700132A01KC	Class I	N/A	MDD self-certified
Breath Trainers 5055788700015301GV	Class I	N/A	MDD self-certified
ProVu Accessories – Displays 5055788700015501H7	Class I	N/A	MDD self-certified
ProVu Accessories – Wrist Holders 5055788700015503HB	Class I	N/A	MDD self-certified
ProVu Accessories – Stands 5055788700015502H9	Class I	N/A	MDD self-certified

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
22/04/2024	Version 1	Initial issue