

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
Single Registration Number (SRN): Not issued

Flexicare Medical Limited declares that the devices listed below meet the provisions of Regulation (EU) 2017/745 (as amended) of the European Parliament and of the Council Concerning Medical Devices.

Conformity Assessment Route: Annex IV
Certificate Number(s): N/A

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:

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For and on behalf of Flexicare Medical Limited,

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Managing Director

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Director

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Suction Tubing (Non-Sterile, Single Use)

TF: 003

Basic UDI-DI / GMN: 5055788700000301FF

Intended use: 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
10830-5	Suction Tube with Bubble 30m Coil 5mm ID	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
10830-7	Suction Tube with Bubble 30m Coil 7mm ID	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
838-368	Suction tubing 10', 3/16" ID	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
838-433	Suction tubing 10', 9/32" ID	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
838-513	Suction tubing 12', 1/4" ID	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
Z152020A	Suction Tube 2000 X 7mm Bulk Pack	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
Z152027A	Suction Tube 2700 X 7mm Bulk Pack	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
Z152030A	Suction Tube 3000 X 7mm Bulk Pack	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
Z152035A	Suction Tube 3500 X 7mm Bulk Pack	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
NF-034	Suction Tubing 0.5m (18")	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N
NF-034U	Suction Tubing 0.5m (18")	Class I (Rule 1)	16779	Suction/irrigation tubing, single-use	N

Drainage Bags – Stands (Non-Sterile, Single Use)

TF: 019

Basic UDI-DI / GMN: 5055788700001901GL

Intended use: A device designed to secure a urine collection bag in a stable position and height to an object other than the patient. It is available in a variety of designs and may be a device intended to attach the bag to objects such as wheelchairs, beds, and chairs occupied by the patient, or it may be a freestanding device with bag-suspending hooks/clips (e.g., portable stand).

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-0012	FlexiHang Bag Hanger (10)	Class I (Rule 1)	41052	Non-wearable urine collection bag holder	N
00-0014	FlexiHang Bag Hanger (100)	Class I (Rule 1)	41052	Non-wearable urine collection bag holder	N
00-0022	Bedside Bag Stand	Class I (Rule 1)	41052	Non-wearable urine collection bag holder	N

Drainage Bags – Securing Devices (Non-Sterile, Single Use)

TF: 019

Basic UDI-DI / GMN: 5055788700001902GN

Intended use: A device designed to secure a urine collection bag in a stable position and height to an object other than the patient. It is available in a variety of designs and may be a device intended to attach the bag to objects such as wheelchairs, beds, and chairs occupied by the patient, or it may be a freestanding device with bag-suspending hooks/clips (e.g., portable stand).

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-0035	Leg Bag Holder - Small	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0035U	Leg Bag Holder - Small	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0036	Leg Bag Holder - Medium	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0036U	Leg Bag Holder - Medium	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0037	Leg Bag Holder - Large	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0037U	Leg Bag Holder - Large	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0038	Leg Bag Holder - X-Large	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0038U	Leg Bag Holder Extra Large	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0032	Lycra Anti-Slip Leg Straps (100)	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0032C	Lycra Anti-Slip Leg Straps (10)	Class I (Rule 1)	31072	Personal device holder, single-use	N
00-0033C	Leg Strap (Neutral) - Pack Of 10 Pairs	Class I (Rule 1)	31072	Personal device holder, single-use	N

Leg Bags (Non-Sterile, Single Use)

TF: 019a

Basic UDI-DI / GMN: 5055788700019A01KS

Intended use: A non-sterile flexible plastic pouch designed to connect to a urinary catheter, a urinary condom catheter, or a urostomy bag, 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-1501DUT	Leg Bag 500ml Short Tube with Fabric Backing Non - Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-1720	Uriflex Long 45cm Tube 750ml Leg Bag Non Sterile	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-1721	Uriflex Short 10cm Tube 750ml Leg Bag Non Sterile	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-1751DUT	Leg Bag 750ml Short Tube with Fabric Backing - Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-2501DUT	Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing - Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-2751DUT	Leg Bag 750ml Long Tube Non Sterile (Omnimedical)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-3501	Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing - Non Sterile	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-3501DUT	Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing - Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-5351DUT	Discreet Leg Bag 350ml Short Tube with Fabric Backing Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-5501DUT	Discreet Leg Bag 500ml Short Tube Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-5751DUT	Discreet Leg Bag 750ml Short Tube with Non Woven Backing (Omnimedical)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-6351DUT	Discreet Leg Bag 350ml Long Tube with Non Woven Backing (Omnimedical)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-6501DUT	Discreet Leg Bag 500ml Long Tube with Fabric Backing Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-6505	Discreet Leg Bag 500ml Extra Long Adjustable Tube with Fabric Backing - Non-Sterile	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-6505DUT	Discreet Leg Bag 500ml Extra Long Adjustable Tube Non Sterile (Huikeshoven)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N
00-6751DUT	Discreet Leg Bag 750 ml Long Tube Non Sterile (Omnimedical)	Class I (Rule 1)	58923	Wearable urine collection bag, open-ended	N

2l Bags – Drainable (Non-Sterile, Single Use)

TF: 019b

Basic UDI-DI / GMN: 5055788700019B01KX

Intended use: A non-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

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Drainable Bags					
00-1202ADUT	F4 2L Drainable Bag Non Sterile (Omnimedical)	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-1202DUT	F4 2L Drainable Bag Non Sterile (Omnimedical)	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-1202LEDUT	F4 2L Drainable Bag with T-Tap Non Sterile (Huikeshoven)	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-1204NS	F4 2L Drainable Bag with T-Tap Non-sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-2206	F3 Hospital Pack –2L Bag with Non-return Valve and T-tap, Non-sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-2206RU	2Lit F3 Drainable Bag With T-Tap Non-Sterile - (Russian)	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
Once Drainable Bags					
00-2203	F2-EZ 2L Once Drainable Bag with Twist-Snap Tap Non-Sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-2203C	F2-EZ 2L Once Drainable Bag with Twist-Snap Tap Non-Sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-2208	F2-EZB 2L Once Drainable Bag with Bottom Twist-Snap Tap Non Sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N
00-2208C	F2-EZB 2L Once Drainable Bag with Bottom Twist-Snap Tap Non Sterile	Class I (Rule 1)	58921	Non-wearable urine collection bag, open-ended	N

2l Bags – Non-Drainable (Non-Sterile, Single Use)

TF: 019b

Basic UDI-DI / GMN: 5055788700019B02KZ

Intended use: A non-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 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-2201	F2 2L Non-Drainable Bag Non-Sterile	Class I (Rule 1)	58917	Non-wearable urine collection bag, closed-ended	N
00-2202C	F2 2L Non-Drainable Bag Non-Sterile	Class I (Rule 1)	58917	Non-wearable urine collection bag, closed-ended	N

Oxygen Therapy Accessories – Nose Clip (Non-Sterile, Single Use)

TF: 029d

Basic UDI-DI / GMN: 5055788700029D01LL**Intended use:** A device intended to be used to compress the nose externally, to ensure that airflow is exclusively conducted through the mouth during examinations of the pulmonary function (e.g., spirometry), and/or to stop nosebleeds (epistaxis). It is typically constructed of plastic with rubber or foam tips. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-41-394	Nose Clip For Use with Pulmonary Function Test Filter	Class I (Rule 1)	10907	Nose clip, single-use	N

Oropharyngeal Airways – Guedel Airways (Non-Sterile, Single Use)

TF: 030a

Basic UDI-DI / GMN: 5055788700030A01JH

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-91-920NS	Guedel Airway Length 8cm Size 2 Bulk Pack Non Sterile	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-91-930NS	Guedel Airway Length 9cm Size 3 Bulk Pack Non Sterile	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N

Oropharyngeal Airways – Berman Airways (Non-Sterile, Single Use)

TF: 030b

Basic UDI-DI / GMN: 5055788700030B01JN

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-90-030	Berman Airway Length 3cm Size 0000	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-040	Berman Airway Length 4cm Size 000	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-050	Berman Airway Length 5cm Size 00	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-060	Berman Airway Length 6cm Size 0	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-070	Berman Airway Length 7cm Size 1	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-080	Berman Airway Length 8cm Size 2	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-090	Berman Airway Length 9cm Size 3	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-100	Berman Airway Length 10 cm Size 4	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-110	Berman Airway Length 11cm Size 5	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-120	Berman Airway Length 12cm Size 6	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-130	Berman Airway Length 13 cm Size 7	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-030U	Berman Airway 30mm Size 0000	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-040U	Berman Airway 40mm Size 000	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-050U	Berman Airway 50mm Size 00	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-060U	Berman Airway 60mm Size 0	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-070U	Berman Airway 70mm Size 1	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-080U	Berman Airway 80mm Size 2	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-090U	Berman Airway 90mm Size 3	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-100U	Berman Airway 100mm Size 4	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-110U	Berman Airway 110mm Size 5	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N
038-90-120U	Berman Airway 120mm Size 6	Class I (Rule 5)	42424	Oropharyngeal airway, single-use	N

Jaw Opener (Non-Sterile, Single Use)

TF: 031a

Basic UDI-DI / GMN: 5055788700031A01JQ

Intended use: A device designed to hold and stabilize an endotracheal (ET) tube when it has been intubated into a patient. It typically consists of straps, pinch rings, cloth ties, or Velcro bands and provides the advantage of easy readjustment of the tube without re-taping or the use of safety pins. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-96-006	Jaw Opener	Class I (Rule 5)	10405	Seizure bite block	N

ET Tube Holder (Non-Sterile, Single Use)

TF: 031b

Basic UDI-DI / GMN: 5055788700031B01JV

Intended use: A device designed to hold and stabilize an endotracheal (ET) tube when it has been intubated into a patient. It typically consists of straps, pinch rings, cloth ties, or Velcro bands and provides the advantage of easy readjustment of the tube without re-taping or the use of safety pins. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-96-001	Adult ET Tube Holder	Class I (Rule 5)	35815	Endotracheal Tube Holder	N

Magill Forceps (Non-Sterile, Single Use)

TF: 031c

Basic UDI-DI / GMN: 5055788700031C01K2

Intended use: A sterile, hand-held instrument used for grasping a tube [e.g., a catheter or an endotracheal (ET) tube] for its insertion and/or extraction into/from the airways, or for grasping obstructive objects for their removal from the airways. Commonly known as a Magill's forceps, it typically has a scissors-like design with ring handles and is made of strong disposable plastic materials or stainless steel. It is available in various sizes and the working end will typically have grasping blades that have small ringed loops or S-shaped distal working ends. The blades are serrated to provide extra grip. It is typically used by emergency medical services (EMS). This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
042-411	Magill Forceps Adult – 25cm	Class 1 (Rule 5)	33089	Airway tube forceps, single-use	N
042-412	Magill Forceps Child – 20cm	Class 1 (Rule 5)	33089	Airway tube forceps, single-use	N
042-413	Magill Forceps Infant – 15cm	Class 1 (Rule 5)	33089	Airway tube forceps, single-use	N

Manual Resuscitators – Skin Temperature Probes (NeoForce) (Non-Sterile, Single Use)

TF: 033

Basic UDI-DI / GMN: 5055788700003301G4

Intended use: A non-sterile assembly of devices designed to conduct air or oxygen (O₂) enriched gases and additional gases [e.g., nitrous oxide (N₂O), halogenated gases] from a ventilator to a patient. It includes breathing tubes, a Y-piece connector, and provides connections for devices that humidify, deliver medication, and monitor gas concentration or pressure within the breathing circuit; some types may include an integrated heating wire powered by a connected humidifier intended to warm breathing gases as they enter the patient's airway. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
NF-023	Disposable Skin Temperature Probes	Class I (Rule 1)	61170	Electrical probe/electrode conductive pad	N
NF-023U	Disposable Skin Temperature Probes	Class I (Rule 1)	61170	Electrical probe/electrode conductive pad	N

Ostomy – One Piece Bags (Non-Sterile, Single Use)

TF: 039

Basic UDI-DI / GMN: 5055788700003901H2

Intended use: A non-sterile plastic pouch designed to be attached with an adhesive to the skin around a faecal stoma and used as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed]. It is a one-piece device, typically having a self-adhesive flange, that is removed and disposed of when full. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
One Piece					
00-911-110	ColoSet C1 Pouch (Clear Film Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-911-110U	ColoSet C1 Pouch (Clear Film Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-911-210	ColoSet C1 Pouch (Clear Film Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-911-210U	ColoSet C1 Pouch (Clear Film Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-912-110	ColoSet C1 Pouch (Opaque Film Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-912-110U	ColoSet C1 Pouch (Opaque Film Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-912-210	ColoSet C1 Pouch (Opaque Film Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-912-210U	ColoSet C1 Pouch (Opaque Film Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-010U	ColoSet D1 Pouch (Clear Film Comfort Net Backing)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-020U	ColoSet D1 Pouch (Clear Film with Non-Woven Backing)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-110	ColoSet D1 Pouch (Clear Film with Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-110U	ColoSet D1 Pouch (Clear Film with Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-210	ColoSet D1 Pouch (Clear Film with Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-931-210U	ColoSet D1 Pouch (Clear Film with Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-932-110	ColoSet Drainable Bag With Comfort Netting, Beige Film+Filter	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-932-110U	ColoSet D1 Pouch (Opaque Film Comfort Net Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-932-210	ColoSet D1 Pouch (Opaque Film with Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-932-210U	ColoSet D1 Pouch (Opaque Film with Non-Woven Backing with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-010	ColoSet Ex Wear D1 Pouch (Clear Film Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-010U	ColoSet Ex Wear D1 Pouch (Clear Film Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-020	ColoSet Ex Wear D1 Pouch (Clear Film-Non-Woven)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-020U	ColoSet Ex Wear D1 Pouch (Clear Film-Non-Woven)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N

00-971-110	ColoSet Ex Wear D1 Pouch (Clear Film-Comfort Net with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-110U	ColoSet Ex Wear D1 Pouch (Clear Film-Comfort Net with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-210	ColoSet Ex Wear D1 Pouch (Clear Film-Non-Woven with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-971-210U	ColoSet Ex Wear D1 Pouch (Clear Film-Non-Woven with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-010	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-010U	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-020	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-020U	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-110	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-110U	ColoSet Ex Wear D1 Pouch (Opaque Film-Comfort Net with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-210	ColoSet Ex Wear D1 Pouch (Opaque Film-Non-Woven with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N
00-972-210U	ColoSet Ex Wear D1 Pouch (Opaque Film-Non-Woven with Filter)	Class I (Rule 1)	31066	One-piece intestinal ostomy bag, closed-ended	N

Ostomy – Two Piece Bags (Non-Sterile, Single Use)

TF: 039

Basic UDI-DI / GMN: 5055788700003902H4

Intended use: A plastic pouch designed to be attached around a faecal stoma for use as a receptacle for faeces following a colostomy [the stool (faeces) being generally well formed]. It consists of two or more separate parts including the pouch with a flange and a base plate, both having a flange locking mechanism. The base plate remains attached around the stoma, typically for 2 to 3 days, when the pouch is removed and replaced. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Two Piece					
00-921-132	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-132U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-138	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-138U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-145	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-145U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-157	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-157U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-170	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-170U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-175	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-921-175U	ColoSet C2 Pouch (Clear Film Comfort Net Back with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-132	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-132U	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-138	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-138U	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-145	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-145U	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-157	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-157U	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-170	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-922-170U	ColoSet C2 Pouch (Opaque Film Comfort Net Backing with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N

00-931-275	ColoSet D2 Pouch (Clear Film Non-Woven Backing with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-931-275U	ColoSet D2 Pouch (Clear Film Non-Woven Backing with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-010U	ColoSet D1 Pouch (Opaque Film Comfort Net Backing)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-020U	ColoSet D1 Pouch (Opaque Film with Non-Woven Backing)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-232	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-232U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 32mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-238	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-238U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 38mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-245	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-245U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 45mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-257	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-257U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 57mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-270	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-270U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 70mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-275	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-932-275U	ColoSet D2 Pouch (Opaque Film Non-Woven Backing with Filter 75mm)	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
Flanges					
00-920-032	ColoSet 2 Piece Flange 32mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-032U	ColoSet 2 Piece Flange 32mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-038	ColoSet 2 Piece Flange 38mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-038U	ColoSet 2 Piece Flange 38mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-045	ColoSet 2 Piece Flange 45mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-045U	ColoSet 2 Piece Flange 45mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-057	ColoSet 2 Piece Flange 57mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-057U	ColoSet 2 Piece Flange 57mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-070	ColoSet 2 Piece Flange 70mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-070U	ColoSet 2 Piece Flange 70mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-075	ColoSet 2 Piece Flange 75mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-920-075U	ColoSet 2 Piece Flange 75mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-032	ColoSet Extended Wear 2 Piece Flange 32mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N

00-960-032U	ColoSet Extended Wear 2 Piece Flange 32mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-038	ColoSet Extended Wear 2 Piece Flange 38mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-038U	ColoSet Extended Wear 2 Piece Flange 38mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-045	ColoSet Extended Wear 2 Piece Flange 45mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-045U	ColoSet Extended Wear 2 Piece Flange 45mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-057	ColoSet Extended Wear 2 Piece Flange 57mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-057U	ColoSet Extended Wear 2 Piece Flange 57mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-070	ColoSet Extended Wear 2 Piece Flange 70mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N
00-960-070U	ColoSet Extended Wear 2 Piece Flange 70mm	Class I (Rule 1)	31067	Multiple-piece intestinal ostomy bag, closed-ended	N

Ostomy – Securing Devices (Non-Sterile, Single Use)

TF: 039

Basic UDI-DI / GMN: 5055788700003903H6

Intended use: A non-sterile piece, strip, or band of material designed to apply pressure to stabilize an ostomy bag (receptacle that collects bodily waste through a stoma) to a patient's body.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Accessories					
00-900-010	Stoma Care Belt With Adjustable Strap	Class I (Rule 1)	43370	Ostomy bag pressure bandage	N
00-900-010U	Stoma Care Belt With Adjustable Strap	Class I (Rule 1)	43370	Ostomy bag pressure bandage	N
00-900-010LX	Large Stoma Care Belt With Adjustable Strap	Class I (Rule 1)	43370	Ostomy bag pressure bandage	N
00-900-010LXU	Large Stoma Care Belt With Adjustable Strap	Class I (Rule 1)	43370	Ostomy bag pressure bandage	N

Ostomy – Pouch Clamp (Non-Sterile, Single Use)

TF: 039

Basic UDI-DI / GMN: 5055788700003904H8**Intended use:** A non-sterile device used to allow the emptying and/or reclosure of an open-ended ostomy bag

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-900-011	ColoSet Drainable Pouch Clamp	Class I (Rule 1)	37502	Ostomy bag closure device	N
00-900-011U	ColoSet Drainable Pouch Clamp	Class I (Rule 1)	37502	Ostomy bag closure device	N

Ostomy – Paste (Non-Sterile, Single Use)

TF: 039

Basic UDI-DI / GMN: 5055788700003905HA**Intended use:** A non-sterile substance (e.g., gel, aerosol) intended to adhere a medical device (e.g., dressing, ostomy device, aesthetic restoration prosthesis) to the skin surface; it is not intended for invasive/surgical use but may be intended for other non-patient contact uses. It may be used in the home or healthcare facility. After application, this device cannot be reused

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
00-900-020	STOMA CARE PASTE 60g	Class I (Rule 1)	10035	Skin surface device adhesive, non-sterile	N

Ventilator Circuits – CPAP Mask Head Strap (Non-Sterile, Single Use)

TF: 056b

Basic UDI-DI / GMN: 5055788700056B01LN**Intended use:** A non-sterile, non-latex strap/head harness intended to hold an anaesthesia mask in position on a patient's face. It is typically wrapped around the patient's head and affixed to the mask. It is typically used for anaesthesia of long duration. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-35-934	Head Strap for Adult Medium CPAP Mask	Class I (Rule 1)	60882	Anaesthesia mask strap, single-use	N
038-35-935	Head Strap for Adult Large CPAP Mask	Class I (Rule 1)	60882	Anaesthesia mask strap, single-use	N

LarySeal Cuff Inflator (Non-Sterile, Reusable)

TF: 082a

Basic UDI-DI / GMN: 5055788700082A01LN

Intended use: A manually-powered device designed to instil air into the cuff of an in situ endotracheal (ET)/endobronchial tube/Laryngeal Mask Airway. The purpose of the cuff is to provide an adequate seal for positive pressure ventilation and to prevent aspirated secretions from passing into the lungs.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-94-001	LarySeal Colour Coded Cuff Inflator	Class I (Rule 1)	35401	Endotracheal tube cuff inflator	N
038-94-001U	LarySeal Colour Coded Cuff Inflator	Class I (Rule 1)	35401	Endotracheal tube cuff inflator	N

Enema and Douche Devices (Non-Sterile, Single Use)

TF: 115

Basic UDI-DI / GMN: 5055788700011501GB

Intended use: A collection of devices intended to be used to deliver an injection of fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine. It includes a fluid reservoir (e.g., enema bag) which acts as a gravity-flow chamber, and typically includes enema tube(s) and enema tip; it may be prefilled with a non-medicated enema solution and may be available preassembled. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
01-Q06	EpiFlex Cuffed Enema Tip	Class I (Rule 5)	35050	Gravity enema set	N
01-Q07	EpiFlex Extra Large Enema Air Tip	Class I (Rule 5)	35050	Gravity enema set	N
01-Q08	EpiFlex Enema Tip	Class I (Rule 5)	35050	Gravity enema set	N
01-Q09	EpiFlex Enema Air-Tip	Class I (Rule 5)	35050	Gravity enema set	N
01-Q11	EpiFlex Cuffed Air-Tip	Class I (Rule 5)	35050	Gravity enema set	N
01-Q12	EpiFlex Enema Bag	Class I (Rule 2)	35050	Gravity enema set	N
01-Q14	EpiFlex Airline Puffer	Class I (Rule 2)	35050	Gravity enema set	N
01-Q15	EpiFlex Single Shot Cuff Inflator	Class I (Rule 1)	35050	Gravity enema set	N
01-Q40	EpiFlex Barium Straw	Class I (Rule 2)	35050	Gravity enema set	N

BritePro Solo, Handle & LS (Non-Sterile, Single Use)

TF: 120a

Basic UDI-DI / GMN: 5055788700120A01JK

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
<i>BritePro Solo</i>					
040-309NS	BritePro Solo Fibre Optic Single Use Mini Laryngoscope Handle Non Sterile	Class I (Rule 13)	47806	Laryngoscope Handle, Single Use	Y
040-310NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle Non Sterile	Class I (Rule 13)	47806	Laryngoscope Handle, Single Use	Y
040-03-0000NS	BritePro Solo Single Use Fibre Optic Stubby Handle Non Sterile	Class I (Rule 13)	47806	Laryngoscope Handle, Single Use	Y
040-331NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Macintosh Blade Size 1 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-332NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Macintosh Blade Size 2 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-333NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Macintosh Blade Size 3 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-334NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Macintosh Blade Size 4 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-335NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Macintosh Blade Size 3.5 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-340NNS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 00 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-340NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 0 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-341NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 1 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-342NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 2 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-343NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 3 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-344NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Miller Blade Size 4 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-350NNS	BritePro Solo Fibre Optic Single Use Mini Laryngoscope Handle and Miller Blade Size 00 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y

040-350NS	BritePro Solo Fibre Optic Single Use Mini Laryngoscope Handle and Miller Blade Size 0 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-351NS	BritePro Solo Fibre Optic Single Use Mini Laryngoscope Handle and Miller Blade Size 1 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-890U	BritePro Solo Single-Use Fiber Optic Box Set - Pro Mac 3, 4 & Miller 00, 2	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
Light Source & Handle					
040-792	BritePro Fibre Optic Single Use Laryngoscope Handle Lightsource	Class I (Rule 13)	38659	Intubation light source	Y
040-792U	BritePro Single-Use Fiber Optic Lightsource	Class I (Rule 13)	38659	Intubation light source	Y
040-793	Light Source with Battery	Class I (Rule 13)	38659	Intubation light source	Y
040-795	BritePro Fibre Optic Single Use Laryngoscope Handle Lightsource with Battery	Class I (Rule 13)	47806	Laryngoscope Handle, Single Use	Y

Single Use Blades – Fibre Optic (Non-Sterile, Single Use)

TF: 120b

Basic UDI-DI / GMN: 5055788700120B01JQ

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
040-611	BriteBlade Non-Metallic Disposable Fibre Optic Macintosh Blade Size 1	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-611U	BriteBlade Single-Use Fiber Optic Plastic Blade Mac 1	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-612	BriteBlade Non-Metallic Disposable Fibre Optic Macintosh Blade Size 2	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-612U	BriteBlade Single-Use Fiber Optic Plastic Blade Mac 2	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-613	BriteBlade Non-Metallic Disposable Fibre Optic Macintosh Blade Size 3	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-613U	BriteBlade Single-Use Fiber Optic Plastic Blade Mac 3	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-614	BriteBlade Non-Metallic Disposable Fibre Optic Macintosh Blade Size 4	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-614U	BriteBlade Single-Use Fiber Optic Plastic Blade Mac 4	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-520	Disposable Fibre Optic Miller Size 0 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-520U	BriteBlade Single-Use Fiber Optic Plastic Blade Miller 0	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-521	Disposable Fibre Optic Miller Size 1 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-521U	BriteBlade Single-Use Fiber Optic Plastic Blade Miller 1	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-522	Disposable Fibre Optic Miller Size 2 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-522U	BriteBlade Single-Use Fiber Optic Plastic Blade Miller 2	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-523U	BriteBlade Single-Use Fiber Optic Plastic Blade Miller 3	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-0810NS	BriteBlade Pro Single Use Fibre Optic Seward Blade Size 1 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-0820NS	BriteBlade Pro Single Use Fibre Optic Seward Blade Size 2 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1100NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 1.5 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N

040-00-1101NS	BriteBlade Pro Single Use Fibre Optic Robertshaw Blade Size 0 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1210NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 1 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1215NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 1.5 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1220NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 2 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1230NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-00-1240NS	BriteBlade Pro Single Use Fibre Optic Wis-Hipple Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-520S	Disposable Fibre Optic Miller Size 0 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-521S	Disposable Fibre Optic Miller Size 1 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-522S	Disposable Fibre Optic Miller Size 2 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-523	Disposable Fibre Optic Miller Size 3 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-523S	Disposable Fibre Optic Miller Size 3 Blade	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-620	BriteBlade Non-Metallic Disposable Fibre Optic Blade Miller Size 0	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-621	BriteBlade Non-Metallic Disposable Fibre Optic Blade Miller Size 1	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-622	BriteBlade Non-Metallic Disposable Fibre Optic Blade Miller Size 2	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-623	BriteBlade Non-Metallic Disposable Fibre Optic Blade Miller Size 3	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-673NS	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-674NS	BriteBlade Pro Single Use Fibre Optic Polio Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-683NS	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-684NS	BriteBlade Pro Single Use Fibre Optic Kessel Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-711NS	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 1 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-712NS	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 2 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-713NS	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-714NS	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N

040-715NS	BriteBlade Pro Single Use Fibre Optic Macintosh Blade Size 3.5 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-716NS	BriteBlade Pro Single Use Fibre Optic Macintosh Strong Curve Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-720NNS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 00 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-720NS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 0 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-721NS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 1 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-722NS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 2 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-723NS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-724NS	BriteBlade Pro Single Use Fibre Optic Miller Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-733NS	BriteBlade Pro Single Use Fibre Optic Flexible McCoy Type Blade Size 3 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-734NS	BriteBlade Pro Single Use Fibre Optic Flexible McCoy Type Blade Size 4 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-741NS	BriteBlade Pro Fibre Optic Single Use Laryngoscope Phillips Blade Size 1 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N
040-742NS	BriteBlade Pro Fibre Optic Single Use Laryngoscope Phillips Blade Size 2 (Non-Sterile)	Class I (Rule 5)	46828	Laryngoscope Blade, Single Use	N

Single Use Blades – Conventional (Non-Sterile, Single Use)

TF: 120b

Basic UDI-DI / GMN: 5055788700120B02JS

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
040-431	Macintosh Conventional Single Use Laryngoscope Blade Size 1	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-432	Macintosh Conventional Single Use Laryngoscope Blade Size 2	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-433	Macintosh Conventional Single Use Laryngoscope Blade Size 3	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-434	Macintosh Conventional Single Use Laryngoscope Blade Size 4	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-440	Miller Conventional Single Use Laryngoscope Blade Size 0	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-441	Miller Conventional Single Use Laryngoscope Blade Size 1	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-442	Miller Conventional Single Use Laryngoscope Blade Size 2	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-443	Miller Conventional Single Use Laryngoscope Blade Size 3	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y
040-444	Miller Conventional Single Use Laryngoscope Blade Size 4	Class I (Rule 5 & 13)	46828	Laryngoscope Blade, Single Use	Y

BritePro Omni (Non-Sterile, Single Use)

TF: 120c

Basic UDI-DI / GMN: 5055788700120C01JV

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
BritePro Omni – Standard handle					
040-04-0110 NS	BritePro Omni Single Use Laryngoscope Handle and Macintosh Blade Size 1 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0120 NS	BritePro Omni Single Use Laryngoscope Handle and Macintosh Blade Size 2 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0130 NS	BritePro Omni Single Use Laryngoscope Handle and Macintosh Blade Size 3 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0140 NS	BritePro Omni Single Use Laryngoscope Handle and Macintosh Blade Size 4 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0420 NS	BritePro Omni Single Use Laryngoscope Handle and Miller Blade Size 2 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0430 NS	BritePro Omni Single Use Laryngoscope Handle and Miller Blade Size 3 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-04-0440 NS	BritePro Omni Single Use Laryngoscope Handle and Miller Blade Size 4 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
BritePro Omni – Mini handle					
040-06-0110 NS	BritePro Omni Single-Use Laryngoscope Mini Handle with Mac 1 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-06-0400 NS	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 00 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-06-0401 NS	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 0 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-06-0410 NS	BritePro Omni Single-Use Laryngoscope Mini Handle with Miller 1 Non-Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y

Reusable Laryngoscopes (Non-Sterile, Reusable)

TF: 120d

Basic UDI-DI / GMN: 5055788700120D01K2

Intended use: 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Reusable Conventional Handle					
040-021	Reusable Conventional Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-021U	Reusable Conventional Laryngoscope Standard Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-022	Reusable Conventional Mini Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-022U	Reusable Conventional Laryngoscope Penlight Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-023	Reusable Conventional Stubby Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-023U	Reusable Conventional Laryngoscope Stubby Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-011	Reusable Conventional Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-011U	Reusable Conventional Laryngoscope Standard Handle Satin	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-012	Reusable Conventional Mini Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-012U	Reusable Conventional Laryngoscope Penlight Handle Satin	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-013	Reusable Conventional Stubby Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
Reusable Conventional Standard Blades					
040-110	Reusable Conventional Laryngoscope Blade Macintosh Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-110U	Reusable Conventional Blade Mac 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-111	Reusable Conventional Laryngoscope Blade Macintosh Size 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-111U	Reusable Conventional Blade Mac 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-112	Reusable Conventional Laryngoscope Blade Macintosh Size 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-112U	Reusable Conventional Blade Mac 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-113	Reusable Conventional Laryngoscope Blade Macintosh Size 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-113U	Reusable Conventional Blade Mac 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-129	Reusable Conventional Laryngoscope Blade Miller Size 00	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-129U	Reusable Conventional Blade Miller 00	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y

040-130	Reusable Conventional Laryngoscope Blade Miller Size 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-130U	Reusable Conventional Blade Miller 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-131	Reusable Conventional Laryngoscope Blade Miller Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-131U	Reusable Conventional Blade Miller 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-132	Reusable Conventional Laryngoscope Blade Miller Size 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-132U	Reusable Conventional Blade Miller 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-133	Reusable Conventional Laryngoscope Blade Miller Size 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-133U	Reusable Conventional Blade Miller 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-134	Reusable Conventional Laryngoscope Blade Miller Size 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-134U	Reusable Conventional Blade Miller 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-192U	Reusable Conventional Blade American Mac 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-193U	Reusable Conventional Blade American Mac 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-194U	Reusable Conventional Blade American Mac 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
Reusable Conventional Speciality Blades					
040-230	Reusable Conventional Laryngoscope Blade Robertshaw Size 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-230U	Reusable Conventional Blade Robert Shaw 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-231	Reusable Conventional Laryngoscope Blade Robertshaw Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-231U	Reusable Conventional Blade Robert Shaw 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-261	Reusable Conventional Laryngoscope Blade Seward Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-262	Reusable Conventional Laryngoscope Blade Seward Size 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-250	Reusable Conventional Laryngoscope Blade Wisconsin Size 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-250U	Reusable Conventional Blade Wisconsin 0	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-251	Reusable Conventional Laryngoscope Blade Wisconsin Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-252	Reusable Conventional Laryngoscope Blade Wisconsin Size 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-252U	Reusable Conventional Blade Wisconsin 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-253	Reusable Conventional Laryngoscope Blade Wisconsin Size 3	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-254	Reusable Conventional Laryngoscope Blade Wisconsin Size 4	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-281	Reusable Conventional Laryngoscope Blade Phillips Size 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-281U	Reusable Conventional Blade Phillips 1	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
040-282U	Reusable Conventional Blade Phillips 2	Class I (Rule 5 & 13)	46827	Laryngoscope Blade, Reusable	Y
Reusable Conventional Box Set – Handles and Blades					

040-239	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Blades Sizes 2 + 3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-239U	Reusable Conventional Box Set Handle + Blades Mac 2, 3 & 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-240	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Blades Sizes 1 + 2 + 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-240U	Reusable Conventional Box Set Handle + Blades Mac 1, 2 & 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-241	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Blades Sizes 1 + 2 + 3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-241U	Reusable Conventional Box Set Handle + Blades Mac 1, 2, 3 & 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-220	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 1 + 2 + 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-221	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 1 + 2 + 3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-222	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 2 + 3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-223	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 0 + 1 + 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-224	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 0 + 1 + 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-226	Box Set Conventional Reusable Handle with Knurled Finish and Miller Blade Sizes 00 + 0 + 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-242	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Sizes 1 2 3 + 4 and Miller 0	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-243	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Sizes 2 3 + 4 and Miller 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-245	Box Set Conventional Reusable Laryngoscope Knurled Handle and Macintosh Sizes 3 + 4 and Miller 0	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-837	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Size 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-838	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Size 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-839	Box Set Fibre Optic Reusable Laryngoscope Knurled Handle with Flexible McCoy Type Blade Sizes 3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-860MAX	Box Set BritePro Max Led Fibre Optic Reusable Standard Handle Laryngoscope Kit A	Class I (Rule 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-962	Box Set Laryngoscope Fibre Optic Knurled Mini Handle + Miller Blade Sizes 00+0 and Mac Blade Size1+2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
Reusable Fibre Optic Handles					
040-811	Reusable Fibre Optic Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y

040-811U	Reusable Fiber Optic Standard Laryngoscope Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-812	Reusable Fibre Optic Mini Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-812U	Reusable Fiber Optic Penlight Laryngoscope Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-821	Reusable Fibre Optic Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-821U	Reusable Fiber Optic Standard Laryngoscope Handle Satin	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-822	Reusable Fibre Optic Mini Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-822U	Reusable Fiber Optic Penlight Laryngoscope Handle Satin	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-823	Reusable Fibre Optic Stubby Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-823U	Reusable Fiber Optic Stubby Laryngoscope Handle Rough	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-824	Reusable Fibre Optic Stubby Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-824U	Reusable Fiber Optic Stubby Laryngoscope Handle Satin	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-014	Conventional Reusable Large Laryngoscope Handle Satin Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
Reusable Fibre Optic Box Set – Handles and Blades					
040-866INT	G\S Boxed set F/O Integra Blades 1,2,3 + 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-860	Box Set Fibre Optic Laryngoscope Kit A	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-860U	Reusable Fiber Optic Box Set Standard Rough Handle + Blades Mac 1, 2 & 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-861	Box Set Fibre Optic Laryngoscope Kit B	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-861U	Reusable Fiber Optic Box Set Standard Rough Handle + Blades Mac 1, 2, 3 & 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-861B	Box Set Fibre Optic Laryngoscope Kit C	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-862	Box Set Fibre Optic Laryngoscope Kit D	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-862U	Reusable Fiber Optic Box Set Standard Rough Handle + Blades Mac 2, 3 & 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-866	Box Set Laryngoscope Fibre Optic Macintosh Blade 1+2+3+4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-888	Box Set Laryngoscope Fibre Optic Satin Handle with Mac Blade Size 1+2+3+4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-985	Box Set Laryngoscope Fibre Optic Laryngoscope Handle with Integra Macintosh Blades Sizes 1 2 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-877	Box Set Laryngoscope Fibre Optic Handle with Miller Blade Sizes 2 and 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-878	Box Set Laryngoscope Fibre Optic Handle with Miller Blade Sizes 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-879	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 2 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y

040-884	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 1 2 and 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-880	Box Set Laryngoscope Fibre Optic Knurled Handles - Standard Mini and Stubby	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-880U	Reusable Fiber Optic Box Set Rough Handles - Standard, Penlight & Stubby	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-863	Box Set Fibre Optic Laryngoscope with Mini Handle Kit A	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-864	Fibre Optic Laryngoscope with Standard Handle Kit E	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-866	Box Set Laryngoscope Fibre Optic Macintosh Blade 1+2+3+4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-872	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 0 1 and 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-873	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 00 0 1 and 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-874	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 00 0 1 2 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-874U	Reusable Fiber Optic Box Set Standard Rough Handle + Blades Miller 00, 0, 1, 2, 3 & 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-875	Box Set Laryngoscope Fibre Optic Satin Handle with Miller Blade Sizes 00 0 1 2 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-876	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 0 1 2 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-895	Box Set Laryngoscope Fibre Optic Knurled Handle with Miller Blade Sizes 0 1 2 and 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-897	Box Set Laryngoscope Fibre Optic Knurled Stubby Handle with Miller Blade Sizes 0 1 and 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-898	Box Set Laryngoscope Fibre Optic Knurled Stubby Handle with Miller Blade Sizes 00 0 and 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-899B	Box Set Laryngoscope Fibre Optic Knurled Stubby Handle and Miller Blade Sizes 00-0-1 + 2+Spare Bulb	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-960	Box Set Laryngoscope Fibre Optic Knurled Mini Handle + Miller Blade Sizes 0 + 00	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-961	Box Set Laryngoscope Fibre Optic Knurled Mini Handle + Miller Blade Sizes 00 + 0 + 1 + 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-965	Box Set Laryngoscope Fibre Optic Satin Mini Handle + Miller Blade Sizes 0 + 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-966	Box Set Laryngoscope Fibre Optic Knurled Mini Handle + Miller Blade Sizes 00+0+1 and Mac Blade Size1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-973	Boxed Set Laryngoscope Conventional Knurled Mini Handle with Miller Blade Sizes 0 + 1 + 2 + 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-985MAX	Box Set BritePro Max Led Fibre Optic Laryngoscope Kit A	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y

040-986MAX	Box Set Laryngoscope Fibre Optic Britepro Max LED Handle & IntegraBlades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-889MAX	Box Set Laryngoscope Fibre Optic Britepro Max Led Handle with Macintosh Blades Sizes 3 and 4	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-861MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle and Reusable Fibre Optic blades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-862 MAX	Box Set BritePro Max Led Fibre Optic Reusable Standard Handle Laryngoscope Kit B	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-869MAX	Box Set BritePro Max Led Fibre Optic Reusable Standard Laryngoscope Kit C	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-871MAX	Box Set BritePro Max Led Fibre Optic Reusable Standard Laryngoscope Kit D	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-895MAX	Box Set Laryngoscope BritePro Max Led Handle with Miller Blade Sizes 0 1 2 and 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-896MAX	Box Set Laryngoscope BritePro Max Led Handle + Miller Blade Size 0 and Mac Blade Sizes 1+2+3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-987MAX	Box Set BritePro Max Led Fibre Optic Laryngoscope Kit C	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-970MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle & IntegraBlades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-971MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle & Reusable Fibre Optic blades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-865MAX	Box Set Laryngoscope Fibre Optic Britepro Max LED Handle & Reusable Fibre Optic blades Set 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-972MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle & IntegraBlades Set 2	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-973MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle & IntegraBlades Set 3	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-990MAX	Box Set Laryngoscope Fibre Optic Britepro Max Stubby LED Handle & Reusable Fibre Optic blades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-991MAX	Box Set Laryngoscope Fibre Optic Britepro Max Stubby LED Handle & IntegraBlades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-988MAX	Box Set Laryngoscope Fibre Optic Britepro Max LED Handle & IntegraBlades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
040-964MAX	Box Set Laryngoscope Fibre Optic Britepro Max Mini LED Handle and Reusable Fibre Optic blades Set 1	Class I (Rule 5 & 13)	15076	Rigid intubation laryngoscope, reusable	Y
Reusable LED Handle – BritePro Max					
040-813	BritePro Max Reusable LED Fibre Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-813U	BritePro Max Reusable LED Fiber Optic Laryngoscope Handle Standard	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-814	BritePro Max Reusable LED Fibre Mini Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-814U	BritePro Max Reusable LED Fiber Optic Laryngoscope Handle Mini	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y

040-815	BritePro Max Reusable LED Fibre Stubby Laryngoscope Handle Knurled Finish	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
040-815U	BritePro Max Reusable LED Fiber Optic Laryngoscope Handle Stubby	Class I (Rule 13)	46830	Laryngoscope Handle, Reusable	Y
041-813	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Standard Handle	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-813U	BritePro Max LED Fiber Optic Reusable Laryngoscope Replacement Light Source for Standard Handle	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-814	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Mini Handle	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-815	BritePro Max LED Fibre Optic Reusable Laryngoscope Replacement Light Source for Stubby Handle	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
Reusable Bulbs					
041-401	Small Krypton Bulb For Use with Standard Miller Blade Sizes 00 0 and 1	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-401U	Small Krypton Bulb For Use with Standard Miller Blade Sizes 00 0 and 1	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-402	Standard Krypton Bulb For Use with Standard Blades	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-402U	Standard Krypton Bulb For Use with Standard Blades	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-601	Halogen Bulb For Use with Fibre Optic Handles	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-601U	Halogen Bulb For Use with Fibre Optic Handles	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y
041-606	Halogen Bulbs For Use with Fibre Optic Handles Pack Of 6	Class I (Rule 13)	60381	Laryngoscope light-emitting cell	Y

Reusable Laryngoscopes – Fibre Optic Blades (Non-Sterile, Reusable)

TF: 120d

Basic UDI-DI / GMN: 5055788700120D02K4

Intended use: 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Reusable Fibre Optic Blades					
040-831	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-832	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-832U	Reusable Fiber Optic Blade Mac 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-833	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-833L	Reusable Fibre Optic Left Handed Laryngoscope Blade Macintosh Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-833U	Reusable Fiber Optic Blade Mac 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-834	Reusable Fibre Optic Laryngoscope Blade Macintosh Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-834U	Reusable Fiber Optic Blade Mac 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-835	Reusable Fibre Optic Laryngoscope Blade Flexible McCoy Type Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-836	Reusable Fibre Optic Laryngoscope Blade Flexible McCoy Type Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-849	Reusable Fibre Optic Laryngoscope Blade Miller Size 00	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-849U	Reusable Fiber Optic Blade Miller 00	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-850	Reusable Fibre Optic Laryngoscope Blade Miller Size 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-850U	Reusable Fiber Optic Blade Miller 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-851	Reusable Fibre Optic Laryngoscope Blade Miller Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-851U	Reusable Fiber Optic Blade Miller 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-852	Reusable Fibre Optic Laryngoscope Blade Miller Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-852U	Reusable Fiber Optic Blade Miller 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-853	Reusable Fibre Optic Laryngoscope Blade Miller Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-853U	Reusable Fiber Optic Blade Miller 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-854	Reusable Fibre Optic Laryngoscope Blade Miller Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-854U	Reusable Fiber Optic Blade Miller 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-891U	Reusable Fiber Optic Blade American Mac 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-892U	Reusable Fiber Optic Blade American Mac 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-893U	Reusable Fiber Optic Blade American Mac 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N

040-894U	Reusable Fiber Optic Blade American Mac 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
Reusable Fibre Optic Speciality Blades					
040-930	Reusable Fibre Optic Laryngoscope Blade Robertshaw Size 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-930U	Reusable Fiber Optic Blade Robert Shaw 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-931	Reusable Fibre Optic Laryngoscope Blade Robertshaw Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-931U	Reusable Fiber Optic Blade Robert Shaw 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-951	Reusable Fibre Optic Laryngoscope Blade Seward Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-951U	Reusable Fiber Optic Blade Seward 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-952	Reusable Fibre Optic Laryngoscope Blade Seward Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-952U	Reusable Fiber Optic Blade Seward 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-920	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-921	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-921U	Reusable Fiber Optic Blade Wisconsin 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-922	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-922U	Reusable Fiber Optic Blade Wisconsin 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-923	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-923U	Reusable Fiber Optic Blade Wisconsin 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-924	Reusable Fibre Optic Laryngoscope Blade Wisconsin Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-924U	Reusable Fiber Optic Blade Wisconsin 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-943	Reusable Fibre Optic Laryngoscope Blade Polio Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-1001U	Reusable Fiber Optic Blade Phillips 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-1002U	Reusable Fiber Optic Blade Phillips 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
Reusable Fibre Optic Integrated Blades – Integra Blade					
040-911	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-911U	IntegraBlade Reusable Fiber Optic Blade Mac 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-912	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-912U	IntegraBlade Reusable Fiber Optic Blade Mac 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-913	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-913U	IntegraBlade Reusable Fiber Optic Blade Mac 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-914	Integrablade Reusable Fibre Optic Laryngoscope Blade Macintosh Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-914U	IntegraBlade Reusable Fiber Optic Blade Mac 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N

040-980N	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 00	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-980	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 0	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-981	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 1	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-982	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 2	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-983	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 3	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N
040-984	Integrablade Reusable Fibre Optic Laryngoscope Blade Miller Size 4	Class I (Rule 5)	46827	Laryngoscope Blade, Reusable	N

NS SU Laryngoscopes (Non-Sterile, Single Use)

TF: 120f

Basic UDI-DI / GMN: 5055788700120F01KC

Intended 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.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX VIII	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Single Use Handles					
040-430	Conventional Single Use Laryngoscope Handle	Class I (Rule 13)	47806	Laryngoscope Handle, Single Use	Y
Single Use Handles and Blades					
040-701	BritePro Complete + Brite Blade Evo Mac Size 1 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-702	BritePro Complete + Brite Blade Evo Mac Size 2 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-703	BritePro Complete + Brite Blade Evo Mac Size 3 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-704	BritePro Complete + Brite Blade Evo Mac Size 4 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-706	BritePro Complete + Brite Blade Evo Miller Size 1 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-707	BritePro Complete + Brite Blade Evo Miller Size 2 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-708	BritePro Complete + Brite Blade Evo Miller Size 3 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-709	BritePro Complete + Brite Blade Evo Miller Size 4 Blade	Class I (Rule 5 & 13)	46828	Rigid intubation laryngoscope, single-use	Y
040-283NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle Blade Size 3 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-284NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle Blade Size 4 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-290NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Robertshaw Blade Size 0 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-291NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Robertshaw Blade Size 1 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-336NS	BritePro Solo Fibre Optic Single Use Laryngoscope Handle and Mac Blade Strong Curve Size 3 Non Sterile	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-436	Conventional Single Use Laryngoscope Handle and Macintosh Blade Size 1	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-437	Conventional Single Use Laryngoscope Handle and Macintosh Blade Size 2	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y

040-438	Conventional Single Use Laryngoscope Handle and Macintosh Blade Size 3	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-439	Conventional Single Use Laryngoscope Handle and Macintosh Blade Size 4	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-445	Single Use Conventional Laryngoscope Handle and Blade Miller Size 1	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-446	Single Use Conventional Laryngoscope Handle and Blade Miller Size 2	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-447	Single Use Conventional Laryngoscope Handle and Blade Miller Size 3	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y
040-448	Single Use Conventional Laryngoscope Handle and Blade Miller Size 4	Class I (Rule 5 & 13)	62918	Rigid intubation laryngoscope, single-use	Y

DualGuard – Endoscopic Bite Block (Non-Sterile, Single Use)

TF: 124

Basic UDI-DI / GMN: 5055788700012401GD

Intended use: A device intended to be inserted into a patient's mouth to maintain oral patency during an endoscopic procedure primarily to protect the endoscope, introduced via the mouth, from the patient's natural tendency to bite down on the instrument, thereby causing damage. The device is also intended to protect the tongue and teeth of the patient during endoscopy. It is a basic device and does not include additional functions/features such as lumen to support introduction of an oxygen (O2) line. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-800	EasyGuard Endoscopy Bite Block Adult with Head Strap	Class I (Rule 5)	10405	Seizure bite block	N
032-10-800U	EasyGuard Adult Endoscopy Bite Block with Adjustable Head Strap	Class I (Rule 5)	10405	Seizure bite block	N

Mediflo Duo – Incentive Spirometer (Non-Sterile, Single Use)

TF: 153

Basic UDI-DI / GMN: 5055788700015301GV**Intended use:** The incentive spirometer is intended to be used by patients following thoracic surgery or in other conditions to assist the lungs in returning to normal functioning. Graduations are for self-motivation of patients and not for diagnostic use. The device is supplied nonsterile.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
700 000 000	Mediflo Duo Breathing Trainer	Class I (Rule 5)	31266	Spirometer, incentive	N

ProVu Accessories – Displays (Non-Sterile, Reusable)

TF: 155

Basic UDI-DI / GMN: 5055788700015501H7**Intended use:** The ProVu Accessories are non-sterile devices intended to be used with ProVu Video Systems to assist with oral, nasal and tracheal intubations.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-990-001	ProVu Reusable 3.5" Video Stylet Display, Charging Dock and 1m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
038-990-001U	ProVu Reusable 3.5" Video Stylet Display, Charging Dock and 1m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
038-990-002	ProVu Reusable 8.0" Video Stylet Display, Charging Cable and 2m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
038-990-002U	ProVu Reusable 8.0" Video Stylet Display, Charging Cable and 2m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
038-990-010	ProVu Charging Dock for 3.5" Display	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-010U	ProVu Charging Dock for 3.5" Display	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-011	ProVu Video Stylet Reusable 1m Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-011U	ProVu Video Stylet Reusable 1m Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-012	ProVu Video Stylet Reusable 2m Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-012U	ProVu Video Stylet Reusable 2m Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-013	ProVu Dual Micro USB 1.5m Charging Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
038-990-013U	ProVu Dual Micro USB 1.5m Charging Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
040-07-0035	ProVu 3.5" Video Laryngoscope Monitor and Charging Dock	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
040-07-0035U	ProVu 3.5" Video Laryngoscope Monitor and Charging Dock	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
040-07-0020	ProVu Universal Reusable 2M Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
040-07-0020	ProVu Universal Reusable 2M Amplifier Extension Cable	Class I (Rule 13)	36545	Basic Power Supply	Y
040-07-0080	ProVu Reusable 8" Display, Charging Cable And 2m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y
040-07-0080U	ProVu Reusable 8" Display, Charging Cable And 2m Amplifier Cable	Class I (Rule 13)	36612	Image Display Monitor, Colour	Y

ProVu Accessories – Stands (Non-Sterile, Reusable)

TF: 155

Basic UDI-DI / GMN: 5055788700015502H9

Intended use: The ProVu Accessories are non-sterile devices intended to be used with ProVu Video Systems to assist with oral, nasal and tracheal intubations.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-990-101	ProVu Display Pole Stand and Articulating Arm	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N
038-990-101U	ProVu Display Pole Stand and Articulating Arm	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N
038-990-102	ProVu Display Table Stand	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N
038-990-102U	ProVu Display Table Stand	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N
038-990-103	ProVu Reusable Table Stand Case for 3.5" Display	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N
038-990-103U	ProVu Reusable Table Stand Case for 3.5" Display	Class I (Rule 1)	42513	Medical Monitor/Light Stand	N

ProVu Accessories – Wrist Holder (Non-Sterile, Single Use)

TF: 155

Basic UDI-DI / GMN: 5055788700015503HB**Intended use:** The ProVu Accessories are non-sterile devices intended to be used with ProVu Video Systems to assist with oral, nasal and tracheal intubations.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-990-100	ProVu Single Use Wrist Holder for 3.5" Display	Class I (Rule 1)	64757	Image Display Monitor Holder	N
038-990-100U	ProVu Single Use Wrist Holder for 3.5" Display	Class I (Rule 1)	64757	Image Display Monitor Holder	N






DOC-000001-Declaration of Conformity for Class I Devices

Final Audit Report

2021-06-18

Created:	2021-06-18
By:	Joel Biddle (joel.biddle@flexicare.com)
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