

Către Agenția Medicamentului și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. din

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** solicit
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a
producătorului **Flexicare Medical Limited, Marea Britanie:**

- Canula Nazala de Flux Inalt, Flexicare, pentru Oxigenoterapie
- Sistem de aspirație cu circuit închis, Flexicare, 14Fr, Endotraheal
- Sistem de aspirație cu circuit închis, Flexicare, 16Fr, Endotraheal
- Tub conector tip Y, Flexicare, d-22 mm
- Masca respiratoare pentru maturi, Flexicare, Nr.3
- Masca respiratoare pentru maturi, Flexicare, Nr.4
- Masca respiratoare pentru maturi, Flexicare, Nr.5
- Masca respiratoare pentru maturi, Flexicare, Nr.6
- Sistem de aspirație cu circuit închis, Flexicare, P/u Traheostomie

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **12.09.2023**

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Șemnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**
Chisinau, Republica Moldova,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului **Flexicare Medical**

Limited, Marea Britanie:

- Canula Nazala de Flux Inalt, Flexicare, pentru Oxigenoterapie
- Sistem de aspirație cu circuit închis, Flexicare, 14Fr, Endotraheal
- Sistem de aspirație cu circuit închis, Flexicare, 16Fr, Endotraheal
- Tub conector tip Y, Flexicare, d-22 mm
- Masca respiratoare pentru maturi, Flexicare, Nr.3
- Masca respiratoare pentru maturi, Flexicare, Nr.4
- Masca respiratoare pentru maturi, Flexicare, Nr.5
- Masca respiratoare pentru maturi, Flexicare, Nr.6
- Sistem de aspirație cu circuit închis, Flexicare, P/u Traheostomie

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătură _____



Data 12.09.2023

LETTER OF AUTHORISATION

The undersigned, FLEXICARE MEDICAL LIMITED, is a company registered in England and Wales with company number 02428573 and with registered address c/o Flexicare (Group) Limited, Cynon Valley Business Park, Mountain Ash, United Kingdom, CF45 4ER ("Flexicare Medical"). The country of manufacture is the United Kingdom. Flexicare Medical hereby certifies that Dita Estfarm LLC, a company registered in Republic of Moldova having its registered address at No. 23 Burebista Street, Chisnau MD – 2032, Republic of Moldova (the "Representative") is authorized to offer the products listed below in Federal Republic of Moldova (the "Territory").

Flexicare Medical attests that its Medical Equipment Items and or parts are new and not repurposed.

Product List

1. Products relating to airway management;
2. Anesthesia breathing systems;
3. Anesthesia component(s);
4. Ventilator breathing systems;
5. Breathing filters;
6. Oxygen & aerosol therapy;
7. Resuscitation; and
8. Suction & urology disposables and devices.

The Representative is authorized to import and sell in Moldova and be responsible for issuing in tenders and issuing quotations against relevant tenders, sales, installing and technical services for all our products, since 2023.

Signed for and on behalf of:



Khashayar Poormand
Managing Director
Flexicare Medical Limited Date:





Subject: Flexicare Medical Limited CE Mark & certificate

To whom it may concern,

We, SGS Belgium NV (CE 1639), Noorderlaan 87, BE-2030 Antwerpen, Belgium (hereafter "SGS"), confirm that we have received an application for CE certification to EU Regulation 2017/745 (hereafter the "MDR") from Flexicare Medical Limited, Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK (hereafter "Flexicare") on the 30th June 2022. This application is currently under review by SGS.

On the 20th March 2023, the EU parliament published Regulation (EU) 2023/607. This regulation amended the transitional provisions of the MDR allowing manufacturers to continue to place CE Marked devices on the market using expired certificates under defined conditions. These conditions are including surveillance activities lead by SGS Belgium NV as Notified body for on-site surveillance audit at Flexicare Medical Limited facilities (last on site audit has been conducted in May 2023 and conclude to maintenance of the certificate), vigilance follow up, change review if any and review of technical file if relevant with the certification cycle.

For Flexicare this extends, subject to certain conditions, the validity of the existing CE Certificates GB19/964677 and GB19/964678 from 07 July 2023 to 31 December 2028. The scopes of these certificates are presented in Table 1 below.

Annex II CE Certificate GB19/964677	Annex V CE Certificate GB19/964678
Sterile devices for use in anaesthesia, emergency and intensive care: Suction catheter; Endotracheal tubes; Laryngeal mask airways; Humidification chambers; Suction Yankauers; Infant nasal CPAP therapy device. Foley Catheter Short Term Use Urinary Catheter Sterile Stoma plugs Sterile and non-sterile devices for use in anaesthesia, emergency and intensive care: Breathing circuits; Humidification circuits;	Carbon dioxide absorbent for use in anaesthesia, emergency and intensive care Sterile single use Urimeter Sterile devices for use in anaesthesia, emergency and intensive care: Bougies; Stylets; Laryngoscopes; Laryngoscope handles and laryngoscope blades; Oropharyngeal Airways; Suction tubing; Nasopharyngeal airways Sterile devices for use in urology: Catheter Valve;

SGS Belgium NV

Certification and Business Enhancement Registered Office: Noorderlaan 87 BE-2030 Antwerpen t +32 (0)3 545 48 48 f +32 (0)3 545 48 49
Boulevard International/Internationalelaan 55D BE-1070 Brussels t+32 (0)2 556 00 40 f +32 (0)3 545 48 49 www.be.sgs.com

Member of the SGS Group

RPR Antwerpen VAT BE 0404 882 750 Belfius 550-3560000-93

Breathing filters; Heat and moisture exchangers (HMEs); Heat and moisture exchange (HME) filters; Nebulisers; Oxygen and aerosol therapy devices. Non-sterile devices for use in anaesthesia, emergency and intensive care: Pocket resuscitation first aid masks; Anaesthesia facemasks; Oxygen tubes; Resus bag resuscitators; Manual resuscitators; Respiratory humidifiers; Endoscopy bite block with O2 delivery and CO2 monitoring; Booster Heater – Respiratory Humidifier.	Intermittent catheters; Urine drainage bags;
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Table 1

For medical device manufacturers whose certificates expired after 20 March 2023 (such as Flexicare whose certificate expired 07 July 2023) the following is required to claim the extended validity of Regulation 2023/607:

Requirement	Confirmation of Requirement
a) The devices must continue to comply with Directive 93/42/EEC (the "MDD")	Flexicare has issued a signed declaration dated 03 July 2023 that it complies with this requirement.
b) There are no significant changes in the design and intended purpose	Flexicare has issued a signed declaration dated 03 July 2023 that it complies with this requirement.
c) The devices shall not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health	Flexicare has issued a signed declaration dated 03 July 2023 that it complies with this requirement.
d) The manufacturer must implement an MDR compliant quality management system by 26 May 2024	Flexicare has issued a signed declaration dated 03 July 2023 that it complies with this requirement.
e) The manufacturer has lodged an application with a Notified Body by 26 May 2024 and has signed the agreement with the Notified Body by 26 September 2024.	SGS confirms that the application from Flexicare was received on the 30 June 2022. The written agreement is pending but is not required until 26 September 2024.



We hope that this letter explains the situation of Flexicare's CE Mark, how they are able to extend the validity of CE Certificates GB19-964677 and GB19-964678 under Regulation 2023/607 and continue to use these certificates to CE Mark devices and place them on the market. Additionally, SGS is not required or able to issue certificates with extended dates as the regulation itself directly extends the validity of the certificates.
Please contact me with any questions regarding this letter.

Yours sincerely

Virginie SILORET
Global medical device certification Manager
SGS Belgium NV NB1639
Phone: +41 22 739 98 58
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Email: virginie.siloret@sgs.com



SGS



SGS Belgium NV

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EC Certificate Full Quality Assurance System: Certificate GB19/964677

The management system of

Flexicare Medical Ltd

Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 21 May 2021 until 07 July 2023
And remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 28 January 1997.

Certification is based on reports numbered GB/PC 05884



Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Flexicare Medical Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 8

Detailed scope



Sterile devices for use in anaesthesia,
emergency and intensive care:
Suction catheter;
Endotracheal tubes;
Laryngeal mask airways;
Humidification chambers;
Suction Yankauers;
Infant nasal CPAP therapy device.
Foley Catheter
Short Term Use Urinary Catheter
Sterile Stoma plugs
Sterile and non-sterile devices
for use in anaesthesia, emergency and intensive care:
Breathing circuits;
Humidification circuits;
Breathing filters;
Heat and moisture exchangers (HMEs);
Heat and moisture exchange (HME) filters;
Nebulisers;
Oxygen and aerosol therapy devices.
Non-sterile devices for use
in anaesthesia, emergency and intensive care:
Pocket resuscitation first aid masks;
Anaesthesia facemasks;
Oxygen tubes;
Resus bag resuscitators;
Manual resuscitators;
Respiratory humidifiers;
Nebuliser compressor;
Endoscopy bite block with O2
delivery and CO2 monitoring;
Booster Heater – Respiratory
Humidifier

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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 the European Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC

Conformity assessment route: Annex II (excluding section 4)
Certificate Number(s): GB19/964877

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

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

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

Flexicare Deutschland GmbH,
Ohlenhohnstrasse 34,
53819 Neunkirchen-Seelscheid,
Germany

For and on behalf of Flexicare Medical Limited:

Hash Poormand (Jul 26, 2023 15:59 GMT+2)

Hash Poormand

Director

Reference: DOC-00000330
Date of Issue: 26 Jul 2023
Place of Issue: Flexicare Medical Limited
Cynon Valley Business Park,
Mountain Ash, CF45 4ER, UK.

Resus Bags - Reusable (Non-Sterile)

TF: 025a

Intended use: A non-sterile, hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O2) from an O2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMND CODE	GMND TERM	ROHS APPLIES Y/N
Single Use					
038-71-840	Adult Single Use Resuscitator Bag with Mask Size 5 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-840P	Adult Single Use Resuscitator Bag with PEEP Valve + Mask Size 5 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-840/10	Adult Single Use Resuscitator Bag with Mask Size 4 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-841	Adult Single Use Resuscitator Bag Mask Oxygen Line and Reservoir Bag No Pressure Relief Valve	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-72-840	Paediatric Single Use Resuscitator Bag with Mask Size 3 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-72-840SP	Paediatric Single Use Resuscitator Bag with 3m Oxygen Line + Reservoir Bag Kit 2	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-72-845	Paediatric Single Use Resuscitator Bag with Mask Sizes 3-2 & 1 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-72-840P	Paediatric Single Use Resuscitator Bag with Mask Size 3 + 3m Oxygen Line + Reservoir Bag Kit 1	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-73-840	Neonatal Single Use Resuscitator Bag with Mask Size 1 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-73-840B	Neonatal Single Use Resuscitator Bag with Mask Size 0 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-845	Resuscitation Pack Single Use Kit 1	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-74-942	Adult, Paediatric & Infant Single Use Resuscitation Pack	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-74-942U	Adult, Paediatric & Infant Single Use Resuscitation Pack	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
New Design Single Use Adult					
038-71-940	Adult Single Use Resuscitator with Pressure Relief 60cmH2O and Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-940U	Adult Single Use Resuscitator + Strap + Pressure Relief 60cmH2O + Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-940/1U	Adult Single Use Resuscitator + Strap + Pressure Relief 60cmH2O + Mask Size 5 + MMS 10ft Line	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-940/1U1	Adult Single Use Resuscitator with Pressure Relief 60cmH2O and Mask Size 4 + 3 m Star Lumen Tube	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-941	Adult Single Use Resuscitator with Pressure Relief 60cmH2O + Mask Size 5 + Manometer	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-943	Adult Single Use Resuscitator without Pressure Relief + Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-944	Adult Single Use Resuscitator without Pressure Relief No Strap + Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-945	Adult Single Use Resuscitator + Pressure Relief 60cmH2O + Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-945U	Adult Single Use Resuscitator + Strap + Pressure Relief 60cmH2O + Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-980	Adult Single Use Resuscitator Bag, Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-980U	Adult Resuscitator, Pressure Relief 60cmH2O, Mask Size 5 w/Corrugated Tubing	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-982	Adult Single Use Resuscitator Bag with Mask Size 5 + 3m Oxygen Line + Reservoir Bag + PEEP Valve	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-982B	Adult Single Use Resuscitator Bag No Pressure Relief, Mask Size 5	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
038-71-983U	Adult Resuscitator, Mask Size 5 w/Corrugated Tubing	Class Ila (Rule 2)	36086	Pulmonary resuscitator, manual, single-use	N
Reusable					
038-71-850	Adult Silicone Resuscitator Bag with Mask Size 5 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-850A	Adult Silicone Resuscitator Bag with Mask Size 5 + 3m Oxygen Line + Reservoir Bag in Carry Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-851	Adult Silicone Resuscitator Bag with Mask Size 5 + 3m Oxygen Line + Reservoir Bag No Pressure Relief Valve	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-850	Paediatric Silicone Resuscitator Bag with Mask Size 3 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-850	Neonatal Silicone Resuscitator Bag with Mask Size 0 + 3m Oxygen Line + Reservoir Bag	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-850A	Paediatric Silicone Resuscitator Bag with Mask Size 3 + 3m Oxygen Line + Reservoir Bag in Carry Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-850A	Neonatal Silicone Resuscitator Bag with Mask Size 0 + 3m Oxygen Line + Reservoir Bag in Carry Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-855	Resuscitation Pack Silicone Reusable Kit 1	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-857	Adult + Paediatric Resuscitator Replacement Kit with 3m Oxygen Line and Reservoir Bag	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-857	Neonatal Reusable Resuscitator Replacement Kit with 3m Oxygen Line and Reservoir Bag	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
New Design Reusable Adult					
038-71-950	Adult Reusable Resuscitator with Pressure Relief 60cmH2O and Mask Size 5	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-951	Adult Reusable Resuscitator with Pressure Relief 60cmH2O + Mask Size 5 + Manometer	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-953	Adult Reusable Resuscitator without Pressure Relief + Mask Size 5	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-970	Adult Reusable Resuscitator Mask Size 5 Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
New Design Reusable Paediatric					
038-72-950	Paediatric Reusable Resuscitator with Pressure Relief 60cmH2O and Mask Size 3	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-951	Paediatric Reusable Resuscitator Manometer Mask Size 3	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-952	Paediatric Reusable Resuscitator PEEP Valve Mask Size 3	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-955	Paediatric Reusable Resuscitator Mask Size 2	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-72-970	Paediatric Reusable Resuscitator + Pressure Relief 60cmH2O Mask Size 3 + 2 Round in Carry Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
New Design Reusable Infant					
038-73-950	Infant Reusable Resuscitator with Pressure Relief 60cmH2O and Mask Sizes 1 + 0 Round	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-951	Infant Reusable Resuscitator Manometer Masks 1 R + 0 R	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-952	Infant Reusable Resuscitator PEEP Valve Masks 1 R + 0 R	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-73-970	Infant Reusable Resuscitator Masks 1 R + 0 R Case	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
Reusable Accessories					
038-71-960	Reusable Manual Resuscitator Replacement Patient End Assembly without Pressure Relief	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-961	Reusable Manual Resuscitator Replacement Patient End Assembly with Pressure Relief Valve 60cmH2O	Class Ila (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N



038-71-952	Reusable Manual Resuscitator Replacement Patient End Assembly with Pressure Relief Valve 40cmH2O	Class IIa (Rule 2)	17591	Pulmonary resuscitator, manual, reusable	N
038-71-965	Reusable Manual Resuscitator Replacement Intake End Assembly	Class IIa (Rule 2)	17591	Pulmonary resuscitator,	N

CO₂ Absorbents (Non-Sterile)

TE-028

Intended use: An absorbent material (e.g., granules of treated soda lime) intended to be placed into a reusable carbon dioxide absorber to remove carbon dioxide (CO₂) from the exhaled gases in a patient breathing circuit by chemical reaction. It is typically available in large plastic containers (e.g., 5 kilograms (Kg) by weight) and poured into clean, reusable absorbers. The absorbent is typically manufactured to change colour during its use (e.g., from white to violet, pink to white, or green to violet) to indicate need for replacement. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	MODEL	CLASSIFICATION UNDER ANNEX IV	GMDS CODE	GMDS TERM	RHS APPLIES
038-05-002	VentSorb Carbon Dioxide Absorbent Pink to White x 2 x 4.5Kg	Pink to White	Class I/a (Rule 2 & 3)	36051	Carbon dioxide absorbent	Y/N
038-05-020U	VentSorb Carbon Dioxide Absorbent Pink to White x 2 x 4.5Kg	Pink to White	Class I/a (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
038-05-004	VentSorb Carbon Dioxide Absorbent White to Violet x 2 x 4.5Kg	White to Violet	Class I/a (Rule 2 & 3)	36051	Carbon dioxide absorbent	N
038-05-004U	VentSorb Carbon Dioxide Absorbent White to Violet x 2 x 4.5Kg	White to Violet	Class I/a (Rule 2 & 3)	36051	Carbon dioxide absorbent	N

CO₂ Monitoring/Oxygen Delivering Nasal Cannula (Non-Sterile)

TF: 029a

Intended use: A non-sterile, semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient, and held in place with a head strap, to simultaneously deliver oxygen (O₂) and allow sampling of exhaled gas for carbon dioxide (CO₂) monitoring through separate prongs. It is available in one-, two-, or four-prong configurations. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	RHOS APPLIES Y/N
Male Luer					
032-10-123	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Male Pigtail Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-123U	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Female Pigtail Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125U	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125A	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125AU	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125CU	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Female Adapter	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-127	Dual Adult Nasal Cannula 3m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-127U	Dual Adult Nasal Cannula 3m Combined O2 Delivery / CO2 Monitoring Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-127A	Dual Adult Nasal Cannula 3m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-126	Dual Adult Oral Nasal Cannula 3m O2 Delivery/CO2 Monitoring, Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-129U	Dual Adult Oral Nasal Cannula 108 Oz Delivery/CO2 Monitoring, Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-186	Dual Adult Oral Nasal Cannula 3m O2 Delivery/CO2 Monitoring, Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-190U	Dual Adult Oral Nasal Cannula 108 Oz Delivery/CO2 Monitoring, Filter, Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-197	Adult Nasal Cannula Split O2 Delivery/CO2 Monitoring 7ft O2 tube, 10ft ML Microstream type Luer	Class I(a) (Rule 5)	36308	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-187U	Adult Nasal Cannula Split O2 Delivery/CO2 Monitoring 7ft O2 tube, 10ft ML Microstream type Luer	Class I(a) (Rule 5)	36308	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-125	Dual Nasal Cannula Pediatric 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-125U	Dual Nasal Cannula Pediatric 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-125A	Dual Nasal Cannula Pediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-125AU	Dual Nasal Cannula Pediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-125CU	Dual Nasal Cannula Pediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Female Adapter	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-13-125	Dual Nasal Cannula Neonatal 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36309	Carbon-dioxide-sampling nasal oxygen cannula	N
032-13-125U	Dual Nasal Cannula Neonatal 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36309	Carbon-dioxide-sampling nasal oxygen cannula	N
032-13-125A	Dual Nasal Cannula Neonatal 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36309	Carbon-dioxide-sampling nasal oxygen cannula	N
Female Luer					
032-10-124	Dual Adult Nasal Cannula 2.1m Combined O2 Delivery / CO2 Monitoring Female Pigtail Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N

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032-10-150U	Adult Nasal Cannula Split O2 Delivery/CO2 Monitoring 14ft O2 tube, 10ft M-Line Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-182	Dual Pediatric Nasal Cannula 2.1m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36308	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-152U	Dual Pediatric Nasal Cannula 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-1621U	Dual Pediatric Nasal Cannula 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Luer, M-H Adapter	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-183	Dual Pediatric Nasal Cannula 4.25m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-183U	Dual Pediatric Nasal Cannula 14ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-12-1831U	Dual Pediatric Nasal Cannula 14ft O2 Delivery/CO2 Monitoring, Filter, Microstream Luer, M-H Adapter	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-13-162	Dual Neonatal Nasal Cannula 2.1m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-13-162U	Dual Neonatal Nasal Cannula 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N



Nasal Cannula - Oxygen (Non-sterile)
TF: 029a

Intended use: A non-sterile, semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient and secured in place by placing around the patients ears and tightening under the chin, to administer oxygen (O2). It is commonly known as "nasal prongs". This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-020	Adult Nasal Cannula	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-020U	Adult Nasal Cannula	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-020FLU	Adult Nasal Cannula Flared without Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-020FC	Adult Nasal Cannula with Flared Tip Curved Prongs	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022	Adult Nasal Cannula with 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022U	Adult Nasal Cannula with Star Lumen O2 Tubing 2.1m & One Standard & One Wide Connector	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022N2	Adult Nasal Cannula with 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022U	Adult Nasal Cannula with 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022S	Adult Nasal Cannula with 5m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-022U	Adult Nasal Cannula with 10m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-0210/2	Adult Nasal Cannula with Star Lumen O2 Tubing 10m & One Standard & One Wide Connector	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-0210/2	Adult Nasal Cannula Flared with 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-0210/2	Adult Nasal Cannula with Flared Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-107	Maxiview Duo Nebulizer & Mouthpiece, Tubing, Filter, and PEP Cap	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-101	Adult Curved Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-101U	Adult Curved Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-102	Adult Nasal Cannula with Soft Tip Curved Prongs	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-102U	Adult Nasal Cannula with Soft Tip Curved Prongs	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103	Paediatric Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103U	Paediatric Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103U	Paediatric Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103STR	Paediatric Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-104	Paediatric Nasal Cannula with Soft Tip Curved Prongs	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-105	Neonatal Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-105U	Neonatal Nasal Cannula with Soft Tip Curved Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-106	Neonatal Nasal Cannula with Soft Tip Curved Prongs	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-106	Adult Nasal Cannula for CO2 Monitoring with 3m Monitoring Line with Male Luer	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-106U	Adult Nasal Cannula for CO2 Monitoring with 3m Monitoring Line with Male Luer	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-109	Adult Nasal Cannula with Combined O2 Delivery / CO2 Monitoring and 2.1m Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-109U	Adult Nasal Cannula with Combined O2 Delivery / CO2 Monitoring and 2.1m Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N

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032-10-114	Adult High Demand Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-114U	Adult High Demand Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-115	Infant Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-115U	Infant Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-115U	Infant Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-116	Premature Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-116U	Premature Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-101/14	Adult Curved Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-101/14U	Adult Curved Nasal Cannula with Soft Tip Prongs and 2.1m Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103/1	Paediatric Nasal Cannula with Soft Tip Curved Prongs and 158 Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103/1	Neonatal Nasal Cannula with Soft Tip Curved Prongs and 158 Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-103/1	Neonatal Nasal Cannula with Soft Tip Curved Prongs and 158 Oxygen Tubing	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-250	NioFlo Cannula Paediatric Small	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-250U	NioFlo Cannula Paediatric Small	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-251	NioFlo Cannula Paediatric Medium	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-251U	NioFlo Cannula Paediatric Medium	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-252	NioFlo Cannula Paediatric Large	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-252U	NioFlo Cannula Paediatric Large	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-250	NioFlo Cannula Micro-Premature	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-251	NioFlo Cannula Micro-Premature	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-251	NioFlo Cannula Premature	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-251U	NioFlo Cannula Premature	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-252	NioFlo Cannula Neonate	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-252U	NioFlo Cannula Neonate	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-253	NioFlo Cannula Infant	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-253U	NioFlo Cannula Infant	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N

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High Flow Nasal Cannula (Non-Sterile)
TF: 029a

Intended use: A non-sterile, semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient, and held in place with a head strap, to administer oxygen (O2). It is commonly known as "nasal prongs". This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-13-150	High Flow Nasal Cannula Premature Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-150U	High Flow Nasal Cannula Premature Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-151	High Flow Nasal Cannula Neonatal Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-151U	High Flow Nasal Cannula Neonatal Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-152	High Flow Nasal Cannula Infant Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-152U	High Flow Nasal Cannula Infant Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-153	High Flow Nasal Cannula Intermediate Infant Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-13-153U	High Flow Nasal Cannula Intermediate Infant Maximum 8 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-150	High Flow Nasal Cannula Paediatric 20 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-150U	High Flow Nasal Cannula Paediatric 20 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-151	High Flow Nasal Cannula Paediatric Small Adult 40Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-151U	High Flow Nasal Cannula Paediatric Small Adult 40Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-150	High Flow Nasal Cannula Adult Maximum 40 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-150U	High Flow Nasal Cannula Adult Maximum 40 Lpm	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-12-240	Pressure Relief Valve For High Flow Oxygen Therapy 40mH2O	Class Ila (Rule 2)	34142	Pressure relief valve, single-use	N
032-12-240U	Pressure Relief Valve For High Flow Oxygen Therapy 40mH2O	Class Ila (Rule 2)	34142	Pressure relief valve, single-use	N
032-10-250	Pressure Relief Valve For High Flow Oxygen Therapy 60mH2O	Class Ila (Rule 2)	34142	Pressure relief valve, single-use	N
032-10-250U	Pressure Relief Valve For High Flow Oxygen Therapy 60mH2O	Class Ila (Rule 2)	34142	Pressure relief valve, single-use	N
032-10-270	VeeFlo Pro High Flow Nasal Cannula Small Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-270U	VeeFlo Pro High Flow Nasal Cannula Small Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-271	VeeFlo Pro High Flow Nasal Cannula Medium Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-271U	VeeFlo Pro High Flow Nasal Cannula Medium Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-272	VeeFlo Pro High Flow Nasal Cannula Large Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-272U	VeeFlo Pro High Flow Nasal Cannula Large Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-272U	VeeFlo Pro High Flow Nasal Cannula Large Adult Plus Adapter	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-160	VeeFlo High Flow Nasal Cannula Small	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-160U	VeeFlo High Flow Nasal Cannula Small	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-161	VeeFlo High Flow Nasal Cannula Medium	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-161U	VeeFlo High Flow Nasal Cannula Medium	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-162	VeeFlo High Flow Nasal Cannula Large	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
032-10-162U	VeeFlo High Flow Nasal Cannula Large	Class Ila (Rule 5)	35201	Basic nasal oxygen cannula	N
010-675	Flexible Locking Connector	Class Ila (Rule 2)	61348	Tubemask breathing circuit connector, single-use, non-sterile	N
010-675U	Flexible Locking Connector	Class Ila (Rule 2)	61348	Tubemask breathing circuit connector, single-use, non-sterile	N
010-676	Flexible Adaptor 15F/6-8mm	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N

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Non-Rebreathing Masks (Non-Sterile)
TF: 029b

Intended use: A non-sterile, flexible, funnel-shaped device designed to be placed over the nose and mouth to deliver air of high oxygen (O2) concentration to a patient's airway. It typically includes two unidirectional valves, one that closes during inspiration to prevent room air mixing with oxygen in a reservoir bag, and one that closes during expiration to prevent exhaled respiratory gases from entering the reservoir bag. It is made of soft, flexible polymers designed to create an airtight seal against the patient's face. It may include tubing, and various valves and connectors, however other respiratory equipment (e.g., nebulizer, humidifier, CPAP device) is not included. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-070	Adult Non Rebreathing Mask with Ear Loops and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-070U	Adult Non Rebreathing Mask with Ear Loops and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-071	Adult Non Rebreathing Mask with Ear Loops	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072U	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072NC	Adult Non Rebreathing Mask with Nose Clip Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072NCNZ	Adult Non Rebreathing Mask with Nose Clip Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072NCNU	Adult Non Rebreathing Mask with Nose Clip Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072NCSTR	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-072SM	Small Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-073	Adult Non Rebreathing Mask with Head Strap	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-073NC	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-073NCNZ	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-073NCNU	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-073NCSTR	Adult Non Rebreathing Mask with Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-076	Adult Non Rebreathing Mask with Ear Loops and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N
032-10-078	Adult Non Rebreathing Mask with Subleak Post Head Strap and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35173	Non-rebreathing oxygen face mask	N

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033-10-014U	Adult Medium Concentration Mask with Ear Loops and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-014V	Adult Medium Concentration Mask with Ear Loops and 3.0m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-014IU	Adult Medium Concentration Mask with Ear Loops and 3.0m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N

Oxygen Mask with CO2 Monitoring (Non-sterile)

TF: 029b

Intended use: A non-sterile, flexible, form-shaped device designed to be placed over the nose and mouth to deliver a proportional mixture of an oxygen (O2) to a patient's airway and allow sampling of exhaled gas for carbon dioxide (CO2) monitoring. It is made of non-conductive, soft, flexible polymers available in a range of sizes, and designed to create an airtight seal against the patient's face. The device may include tubing and various valves and connectors which may allow for connection to a central vacuum system to enable scavenging of residual (waste) anaesthetic gas from a patient in recovery; other respiratory equipment (e.g., nebulizer, humidifier, CPAP device) is not included. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX II	GMGN CODE	GMGN TERM	ROHS APPLIES Y/N
032-10-131	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-133	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-133A	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-135	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Nose Clip with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-135U	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Nose Clip with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-135CU	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Nose Clip with Male Luer Female Adaptor	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-137	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Nose Clip with Male Luer and Filter	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-137U	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Nose Clip with Male Luer and Filter	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-139	Dual Medium Mask 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-141	Dual Medium Mask 2m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-141BU	Dual Medium Mask 10 ft. Combined O2 Delivery / CO2 Monitoring with Male Luer Slip Filter	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-143	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-143U	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-143CU	Dual Mask Paediatric Medium Concentration 10 ft. with Male Luer CO2 Monitoring Line + Female Adaptor	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-145	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-145U	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-145BU	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Male Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-131	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring Male Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-131U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring Male Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-133	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Male Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-133U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Male Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N

033-10-133A	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Male Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-143	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring Male Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-143U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring Male Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-145	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Male Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-145U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Male Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-130	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-132	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Filter with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-132A	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Filter with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-134	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Nose Clip with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-134U	Dual Adult Mask 3m (10') Combined O2 Delivery / CO2 Monitoring Nose Clip with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-136	Dual Adult Mask 2.1m Combined O2 Delivery / CO2 Monitoring Nose Clip with Female Luer and Filter	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-138U	Dual Adult Mask 3m Combined O2 Delivery / CO2 Monitoring Nose Clip with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-138	Dual Medium Mask 2.1m Combined O2 Delivery / CO2 Monitoring Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-140	Dual Medium Mask 2m Combined O2 Delivery / CO2 Monitoring Filter with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-142	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-142U	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-144	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-144U	Dual Mask Paediatric 2.1m Combined O2 Delivery / CO2 Monitoring Filter with Female Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-130	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-130U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-132	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-132U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-132A	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-132AU	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-142	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring Female Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-142U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring Female Luer + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-144	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N

033-12-144U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Female Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-190	Dual Adult Mask 2m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-190U	Dual Adult Mask 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-191	Dual Adult Mask 4.25m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-191U	Dual Adult Mask 14ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-192	Dual Medium Mask 2m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-10-192U	Dual Medium Mask 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-190	Dual Paediatric Mask 2m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-190U	Dual Paediatric Mask 4.25m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-191	Dual Paediatric Mask 7ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
032-12-191U	Dual Paediatric Mask 14ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-190	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-190U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-191	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-10-191U	Adult Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-190	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-190U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 2.1m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N
033-12-191U	Paediatric Dual Mask Combined O2 Delivery / CO2 Monitoring, Microstream type Luer and filter with 3m Oxygen Tubing	Class Ila (Rule 2)	35171	Rebreathing oxygen face mask	N

Venturi Masks (Non-Sterile)

TF: 029b

Intended use: A flexible, form-shaped device designed to be placed over the nose and mouth to deliver a near-precise mixture of air and oxygen (O2) to a patient's airway without the use of a gas mixer. The device typically includes a variety of interchangeable inserts (the venturi) that allow air entrainment in controlled amounts to provide the desired O2 concentration. It is connected to an O2 source with tubing and includes head straps for stabilization. Adaptors are typically included for connection to a humidification source. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX II	GMGN CODE	GMGN TERM	ROHS APPLIES Y/N
037-10-001	Ventimask Fixed Concentration Mask with 24% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-002	Ventimask Fixed Concentration Mask with 28% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-003	Ventimask Fixed Concentration Mask with 35% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-004	Ventimask Fixed Concentration Mask with 40% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-005	Ventimask Fixed Concentration Mask with 60% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-006	Ventimask Fixed Concentration Mask For Home Use with 28% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-007	Ventimask Fixed Concentration Mask without Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-010	Ventimask Fixed Concentration Mask with 31% Venturi Barrel	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-008	Ventimask Fixed Concentration Mask Low O2 Concentration Set with 24% 28% 31% & 35% Venturi	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-009	Ventimask Fixed Concentration Mask High O2 Concentration Set with 40% & 60% Venturi Barrels	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-009U	Ventimask Fixed Concentration Mask High O2 Concentration Set with 40% & 60% Venturi Barrels	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N
037-10-012	Ventimask Fixed Concentration Mask Set 24% 28% 31% 35% 40% & 60% Venturi Barrels	Class Ila (Rule 2)	35175	Venturi oxygen face mask	N

Tracheostomy Masks (Sterile)

TF: 029b

Intended use: A device designed to deliver oxygen or a mixture of oxygen and air to a patient who has a tracheostomy airway. It is connected to an oxygen/medical air source with tubing and is constructed of plastic. The device can be used over a tracheal tube or stoma. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX II	GMGN CODE	GMGN TERM	ROHS APPLIES Y/N
032-10-025TR	Paediatric Tracheostomy Mask with 22mm Swivel Connector and Head Strap	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N

Tracheostomy Masks (Non-Sterile)

TF: 029c

Intended use: A device designed to deliver oxygen or a mixture of oxygen and air to a patient who has a tracheostomy airway. It is connected to an oxygen/medical air source with tubing and is constructed of plastic. The device can be used over a tracheal tube or stoma. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-091	Adult Tracheostomy Mask with 22mm Swivel Connector and Head Strap	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-091U	Adult Tracheostomy Mask with 22mm Swivel Connector and Head Strap	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-092	Paediatric Tracheostomy Mask with 22mm Swivel Connector and Head Strap	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-092U	Paediatric Tracheostomy Mask with 22mm Swivel Connector and Head Strap	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-092Z	Paed Tracheostomy Mask 24% - 60% Venturi Barrels + 15cm Reservoir Tube + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-093	Adult Tracheostomy Mask with MaxNeb Nebuliser	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-093B	Adult Tracheostomy Mask with MaxNeb 90 Nebuliser and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-095	Adult Tracheostomy Mask with 24% 28% 31% 35% 40% & 60% Venturi Barrels	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-095r1	Adult Tracheostomy Mask 24% - 60% Venturi Barrels + 15cm Reservoir Tube + 2.1m Oxygen Tubing	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-096	Adult Tracheostomy Mask with Reducing Adaptor 6mm M to 22mm F and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-096Z	Adult Trach Mask 22mm Swivel Connector/Head Strap/reducing adaptor/2.1m O2 Tubing/Std 6mm Connector	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
032-10-097Z	Paed Trach Mask 22mm Swivel Connector & Head Strap & 2.1m O2 Tubing/ Std 6mm Connector	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N

Gilston T-Piece (Non-Sterile)

TF: 029c

Intended use: T-Piece device that channels supplementary oxygen to patients with tracheostomy tubes. A sliding cover allows easy access for suction and can be closed when not in use. A Venturi can be fitted to one end of the device to provide oxygen at a fixed concentration or combined with a humidity adaptor for humidification. Gilston T-Piece is intended for Adult and Paediatric patients and are supplied non-sterile, for single use only.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
5060	Gilston T-Piece Adult	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N
5061	Gilston T-Piece Paediatric	Class Ila (Rule 2)	35178	Tracheostomy mask, oxygen	N

High Flow Oxygen Therapy Tracheostomy Interface (Non-Sterile)

TF: 029c

Intended use: A length of flexible tube, typically a small bore, thick-walled, anti-kink tubing (to prevent blockage) intended for the delivery of a pure oxygen (O2) or an O2 enriched gas to a mask or nasal cannula, typically during delivery of dry O2 to the patient. The tubing is typically available in standard coil lengths and is cut by clinical staff to appropriate lengths to create an extension or connecting piece. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-165	VeeHo High Flow Tracheostomy Interface	Class Ila (Rule 2)	12875	Oxygen Administration Tubing	N
032-10-165U	VeeHo High Flow Tracheostomy Interface	Class Ila (Rule 2)	12875	Oxygen Administration Tubing	N
032-10-175	VeeHo High Flow Tracheostomy Interface with Adaptor	Class Ila (Rule 2)	12875	Oxygen Administration Tubing	N
032-10-175U	VeeHo High Flow Tracheostomy Interface Plus Adaptor	Class Ila (Rule 2)	12875	Oxygen Administration Tubing	N

Post-Operative Oxygen Therapy (Non-Sterile)

TF: 029d

Intended use: A configuration of corrugated tubing, T-piece connector, Venturi barrel, oxygen tubing and a mask intended to deliver supplementary oxygen to a patient post operation. This is a non-sterile, single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
032-10-529	Oxygen T-piece with 22mm Blank Venturi	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-529A	Oxygen T-Piece with Reducing Adaptor 6mm M to 22mm F + 2.1m Oxygen Tubing	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-524	Oxygen T-Piece with 24% Venturi Barrel	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-528	Oxygen T-Piece with 28% Venturi Barrel	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-531	Oxygen T-Piece with 31% Venturi Barrel	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-535	Oxygen T-Piece with 35% Venturi Barrel	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-540	Oxygen T-Piece with 40% Venturi Barrel and Corrugated Tube	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-541	Oxygen T-Piece with 24% 28% 31% 35% 40% & 60% Venturi Barrels	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-560	Oxygen T-Piece with 60% Venturi Barrel	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-635	FCOT T-Piece with 35% Venturi Barrel and Indicator Bag	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-640	FCOT T-Piece with 40% Venturi Barrel and Indicator Bag	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-660	FCOT T-Piece with 60% Venturi Barrel and Indicator Bag	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-740	FCOT T-Piece Kit with 40% Venturi Barrel Indicator Bag Adult Aerosol Mask and 3.1m O2 Tubing	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-740A	FCOT T-Piece Kit with 40% Venturi Barrel Indicator Bag Adult Aerosol Mask and 3m O2 Tubing	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-741	FCOT T-Piece Kit with 40% Venturi Barrel Indicator Bag Paediatric Aerosol Mask and 2.1m O2 Tubing	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N

Aerosol Therapy Components (Non-Sterile)

TF: 029d

Intended use: A length of flexible tube, typically a small bore, thick-walled, anti-kink tubing (to prevent blockage) intended for the delivery of a pure oxygen (O2) or an O2 enriched gas to a mask or nasal cannula, typically during delivery of dry O2 to the patient. The tubing is typically available in standard coil lengths and is cut by clinical staff to appropriate lengths to create an extension or connecting piece. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Star Lumen Tubing					
032-10-060	Star Lumen Oxygen Tubing 2.1m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060U	Star Lumen Oxygen Tubing 2.1m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060NZ	Star Lumen Oxygen Tubing 2.1m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060J	Star Lumen Oxygen Tubing 2.1m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060r1	Star Lumen 3 Metre Oxygen Tubing with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060Z	Star Lumen Oxygen Tubing 2.1m with Standard Connectors & Reducing Adaptor 6mm M to 22mm F	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060Z5	Star Lumen Oxygen Tubing 7.5m / 25ft with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-060/50	Star Lumen Oxygen Tubing 15m / 50ft with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-062	Star Lumen Oxygen Tubing 4m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-062U	Star Lumen Oxygen Tubing 4m with Standard Connectors	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-063	Star Lumen Oxygen Tubing 2.1m with One Standard and One Wide Connector	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-063U	Star Lumen Oxygen Tubing 7ft with One Standard and One Wide Connector	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-063/40	Star Lumen Oxygen Tubing 4m with One Standard and One Wide Connector	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-059	Star Lumen Oxygen Tubing 100m	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
Oxygen Bubble Tubing					
032-10-069	Oxygen Tubing 1.6m Bubble Type 3mm ID	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-067	Oxygen Tubing 30m Bubble Type 3mm ID	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-067U	Oxygen Tubing 30m Bubble Type 3mm ID	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
032-10-068	Oxygen Tubing 100m Bubble Type 3mm ID	Class Ila (Rule 2)	32202	Aerosol delivery tubing	N
Corrugated Tubing					
038-01-230	Corrugated Tubing Limb 2m 22mm with 2 x 22mm Female Connectors	Class Ila (Rule 2)	63534	Inspiratory/respiratory limb respiratory tubing, single-use, non-sterile	N
032-10-410Z	Corrugated Tubing 5.4m 22mm with 22M to 6M Reducing Adaptor (Blank Venturi) and 1.3m Oxygen Tubing	Class Ila (Rule 2)	63534	Inspiratory/respiratory limb respiratory tubing, single-use, non-sterile	N
Tubing Connections					
032-10-117	Oxygen Tubing T connector	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single use	N
032-10-118	Oxygen Tubing Right Angled Connector	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single use	N
032-10-119	Oxygen Tubing Straight Connector	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single use	N
032-10-110	Oxygen Tubing Swivel Connector	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single use	N
032-10-111	Oxygen Tubing Swivel Connector with Clip	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single use	N

Humidification Components (Non-Sterile)

TF: 029d

Intended use: A device designed to prevent the drying of airway passages associated with the inhalation of oxygen (O2) by adding water vapour to the dry gas as it is passed through, or more seldom, over water. It typically consists of a graduated container (reservoir) for the water, a top piece that functions as a detachable lid (typically a screw lid with a gasight seal), and a tube that protrudes into the water to divert the gas below the water level. This device, commonly known as a bubble humidifier, does not heat the water. It has connectors: 1) one (e.g., a winged nut) that connects to an oxygen therapy flowmeter; and 2) one to which the patient tubing is connected.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Humidity Adaptor					
5506	Humidity Adaptor 22mm	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, non-sterile, single-use	N
Bubble Humidifiers					
032-10-000	Bubble Humidifier 200ml with 6psi Safety Valve For Home Use	Class Ila (Rule 2)	35113	Non-heated, respiratory humidifier	N
032-10-089	Bubble Humidifier 400ml with Fine Diffuser and 4psi Safety Valve For Hospital Use	Class Ila (Rule 2)	35113	Non-heated respiratory humidifier	N



Electrostatic Bacterial Viral Filters (Sterile)

TF: 041b

Intended use: A sterile screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anesthesia and/or endoscopy. It has no additional non-filtering functions. It is a small plastic housing containing a filter which will typically also filter other particulates (e.g., scale). This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDH CODE	GMON TERM	RHHS APPLIES Y/N
Bacterial/Viral Filter Sterile					
038-41-3605TR	VentShield Adult Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3605STR	VentShield Adult Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3605TRJ	VentShield Adult Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3603115TR	VentShield Adult Bacterial Viral Filter with 22FI15F Flexi-Lock Catheter Mount	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-3606STR	VentShield Mini Bacterial Viral Filter with Luer Port and Low Profile Elbow 22FI15F	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3405STR	VentShield Adult Angled Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-365ASTR	VentShield Adult Bacterial Viral Filter with Luer Port + Flexi-Lock Catheter Mount+Low Profile Elbow	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3655STR	VentShield Adult Bacterial Viral Filter with Luer Port	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3655TRJ	VentShield Adult Bacterial Viral Filter with Luer Port	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3653116405TR	VentShield Adult Bacterial Viral Filter with Luer Port + Flexi-Lock Catheter Mount Plus Elbow	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-3455STR	VentShield Adult Angled Bacterial Viral Filter with Luer Port	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-300-000	Bar-Vent Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-300-001	Bar-Vent Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
Bacterial/Viral Filter Sterile Mini					
038-42-3605STR	VentShield Mini Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-3605TRJ	VentShield Mini Bacterial Viral Filter	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-360311STR	VentShield Mini Bacterial Viral Filter + Flexi-Lock Catheter Mount 22FI15F	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-365311STR	VentShield Mini Bacterial Viral Filter with Luer Port	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-3653115TR	VentShield Mini Bacterial Viral Filter with Luer Port + Flexi-Lock Catheter Mount 22FI15F	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-400-000	Bar-Vent S Bacterial Viral Filter Small	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-400-000J	Bar-Vent S Bacterial Viral Filter Small	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-410-000	Bar-Vent S Angled Bacterial Viral Filter Small	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-410-000J	Bar-Vent S Angled Bacterial Viral Filter Small	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-440-000	Bar-Vent S Machine Bacterial Viral Filter Small	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-405-000	Bar-Vent S Bacterial Viral Filter Small with Flexi-Lock Straight Catheter Mount 15FI22F	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N
300-405-015	Bar-Vent S Bacterial Viral Filter Small with Flexi-Lock Straight Catheter Mount 15FI22F	Class I(a) (Rule 2)	60837	Microbial medical gas filter, single-use	N

Electrostatic Bacterial Viral Filters (Non-Sterile)

TF: 041b

Intended use: A non-sterile screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anesthesia and/or endoscopy; it has no additional non-filtering functions. It is a small plastic housing containing a filter which will typically also filter other particulates (e.g., scale). This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX K	OMDN CODE	GMON TERM	RHHS APPLIES Y/N
Bacterial/Viral Filter					
038-41-360	VentShield Adult Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-360 BRZ	VentShield Adult Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-360U	VentShield Adult Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-360/068	VentShield Adult Bacterial Viral Filter with Oxygen / Nitrous Oxide Circuit Mountpiece	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-360/069U	VentShield Adult Bacterial Viral Filter with Oxygen / Nitrous Oxide Circuit Mountpiece	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-360-303	VentShield Adult Bacterial Viral Filter with Luer Lock Elbow Catheter Mount	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-340	VentShield Adult Angled Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-340U	VentShield Adult Angled Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-365	VentShield Adult Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-365U	VentShield Adult Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-345	VentShield Adult Angled Bacterial Viral Filter with Self-Sealing Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-345U	VentShield Adult Angled Bacterial Viral Filter with Self-Sealing Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-345.5	LuerSafe Adult Angled Bacterial Viral Filter with Self-Sealing Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-345.5U	LuerSafe Adult Angled Bacterial Viral Filter with Self-Sealing Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-365L5	LuerSafe Adult Bacterial Viral Filter with Self-Sealing Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-365L5	VentShield Adult Bacterial Viral Filter with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-368U	VentShield Adult Bacterial Viral Filter with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-41-366L5	LuerSafe Adult Bacterial Viral Filter with Self-Sealing Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-300-000	Bar-Vent Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-300-000U	Bar-Vent Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
430-405-000	Bar-Vent S Bacterial Viral Filter Small with Straight Connector 15P/10M	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
450-404-000	Bar-Vent S Bacterial Viral Filter Small with Feed-Lock Catheter Mount with Elbow 15F-22M/15M	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-300-004	Bar-Vent Bacterial Viral Filter with Silicone Connector 22F	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
Bacterial/Viral Filter Mini					
038-42-360	VentShield Mini Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-360U	VentShield Mini Bacterial Viral Filter	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-365	VentShield Mini Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-365U	VentShield Mini Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-365AC	VentShield Mini Bacterial Viral Filter Port Feed-Lock Catheter Mount 22M/15F +	Class Ila (Rule 2)	60837	Microbial medical gas filter, single-use	N

Mechanical Bacterial Viral Filters (Sterile)

TF: 041c

Intended use: A sterile screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anaesthesia and/or endoscopy; it has no additional non-filtering functions. It is a small plastic housing containing a filter which will typically also filter other particulates (e.g., scale). This is a single-use device.

038-42-395LS	LuerSafe Minibacterial Viral Filter with Self-Sealing Luer Port	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-395LS	LuerSafe Mini Bacterial Viral Filter with Self-Sealing Luer Port	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-398	VentShield Mini Bacterial Viral Filter with Luer Port and Low Profile Elbow 22M/15P	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-396U	VentShield Mini Bacterial Viral Filter with Luer Port and Low Profile Elbow 22M/15P	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-366	VentShield Mini Bacterial Viral Filter with Luer Port + Oxygen/Nitrous Oxide Mouthpiece	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
038-42-001	VentShield Adult Bacterial Viral Filter (22F)	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-460-000	Bar-Vent S Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-460-000	Bar-Vent S Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-410-000	Bar-Vent S Angled Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-410-000	Bar-Vent S Angled Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-440-000	Bar-Vent S Machine Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N
301-440-000	Bar-Vent S Machine Bacterial Viral Filter Small	Class IIA (Rule 2)	60837	Microbial medical gas filter, single-use	N

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMON CODE	GMON TERM	RHHS APPLIES Y/N
Adult					
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3705TR	Viral Filter				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3705TR	Viral Filter				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3705TR	Viral Filter				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3745TR	Viral Filter with Luer Port				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3755TR	Viral Filter with Luer Port				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3761TR	Viral Filter Port Swivel Elbow W/Cap F-4, Cath Mount				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3761TR	Viral Filter Port Swivel Elbow W/Cap F-4, Cath Mount				
038-41	HepaShield Adult Pleated Hydrophobic Bacterial	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3761TR	Viral Filter Port Swivel Elbow W/Cap F-4, Cath Mount				
038-41	Adult Pleated Hydrophobic B / V Filter for port + expandable Catheter Mount + dbl Swivel Elbow + Cap	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3761TR	Viral Filter				
038-41	Adult Pleated Hydrophobic Bacterial / Viral Filter with Tethered Cap Post	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3761TR	Viral Filter				
038-41	Adult Pleated Hydrophobic Bacterial / Viral Filter	Class Ila (Rule 2)	80837	Microbial medical gas filter, single-use	N
3705TR	Viral Filter				

Mechanical Bacterial Viral Filters (Non-Sterile)

TF: 041c

Intended use: A non-sterile screening device intended to remove microbes from medical gases to prevent patient exposure during respiration, anaesthesia and/or endoscopy; it has no additional non-filtering functions. It is a small plastic housing containing a filter which will typically also filter other particulates (e.g., scale). This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX X	GMDN CODE	GMDN TERM	RHHS APPLIES Y/N
HepaSShield Adult					
C89-031-370	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-372 BRZ	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-373	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-370S	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-375U	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-375A	HepaSShield Adult Pleated Paper Hydrophobic Bacterial Viral Filter with Luer Port	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-NA	HepaSShield Adult Pleated Hydrophobic Bacterial Viral Filter with Luer Port - Flow-Lock Cam Mount	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-375V	HepaSShield Adult Pleated Hydrophobic Bacterial Viral Filter with Luer Port - Flow-Lock Cam Mount	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N
C89-031-375L	HepaSShield Adult Pleated Hydrophobic Bacterial Viral Filter with Luer Port - Flow-Lock Cam Mount	Class Ila (Rule 2)	D6E3T	Microbial medical gas filter, single-use	N



038-41-376 HepaShield Adult Pleated Hydrophobic Bacterial
Viral Filter Port Swivel Elbow W/Cap F-L Coll.
Mount Class IIa (Rule 2) 60837 Microbial medical gas filter,
single-use N

Nebulisers (Non-Sterile)

TF: 054

Intended use: A collection of devices intended to be connected to a nebulizing system gas compressor or medical gas outlet to create/deliver an aerosol, usually medicated, to the patient's respiratory system. It includes a single-use nebulizing medication chamber, and typically flexible tubing with connectors and/or a mask (e.g., oxygen (O2) mask) or mouthpiece; pharmaceuticals are not included. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMD N CODE	GMD TERM	ROHS APPLIES Y/N
MaxiNeb®					
032-10-003	MaxiNeb Nebuliser	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-003AM	MaxiNeb Nebuliser with 22mm T-Piece and 2.1m Star Lumen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-004	MaxiNeb Nebuliser with T-Piece and Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-004A	MaxiNeb Nebuliser with T-Piece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-004B	MaxiNeb Nebuliser with 010-431 T Piece + Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-005	MaxiNeb Nebuliser with T-Piece Mouthpiece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-005C	MaxiNeb Nebuliser with T-Piece Mouthpiece with 0.15m Corrugated and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-007	Adult Aerosol Face Mask with MaxiNeb Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-007N	Adult Aerosol Face Mask Nose Clip with MaxiNeb Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-011	MaxiNeb Nebuliser Paediatric Aerosol Mask and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-011N2	MaxiNeb Nebuliser Paediatric Aerosol Mask and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-094	Paediatric Tracheotomy Mask with MaxiNeb Nebuliser	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
MaxiNeb® 90					
032-10-015	MaxiNeb 90 Nebuliser	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-015A	MaxiNeb 90 with 18M Connector	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-015AT	MaxiNeb 90 with 18M 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-016	Adult Aerosol Face Mask with MaxiNeb 90 Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-016N	Aerosol Face Mask with nose Clip and MaxiNeb 90 Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-017	Paediatric Aerosol Face Mask with MaxiNeb 90 Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-017/2	Paed Aerosol Face Mask & MaxiNeb 90 & 2.1m Star Lumen O2 Tubing Standard & W/Cap Connector	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-017G	MaxiNeb 90 Nebuliser Kit with Bar-Vent Bacterial Viral Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019	MaxiNeb 90 Nebuliser with T-Piece Mouthpiece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019A	MaxiNeb 90 Nebuliser with Mouthpiece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019A1	MaxiNeb 90 Nebuliser + T-Piece 22M/15F/22M/15F/22F + Mouthpiece + 2.1m Oxygen Tubing Fit All Connector	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019A2	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019B	MaxiNeb 90 Nebuliser Kit with Valved Y-Piece and 2 x T-Pieces and Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-019F	MaxiNeb 90 Nebuliser with Mouthpiece and 2.1m Oxygen Tubing and Bacterial Viral Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023/1	MaxiNeb 90 Nebuliser with Valved T-Piece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023A	MaxiNeb 90 Nebuliser with T-Piece 22M/15F/22M/15F/22F and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N

032-10-023A/1	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F + 22M/15F - 15M Connector and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023A/2	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023B	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023C	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F and Ported Swivel Catheter Mount and 2.1m Oxygen Tube	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023D	MaxiNeb 90 Nebuliser with T-Piece 22M/22M/22F + Flex-Lock Short Catheter Mount + 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023F	MaxiNeb 90 Nebuliser with T-Piece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023H	MaxiNeb 90 Nebuliser with T-Piece and Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-023H/5	MaxiNeb 90 Nebuliser Kit with 5 x T-Pieces and 5 x Mouthpieces and 5x Nebulisers Individually Packed	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-093A	MaxiNeb 90 Nebuliser with T-Piece 22M/15M/15F and Washington T-Piece and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
Large Volume Nebuliser					
032-10-019C	Large Volume Nebuliser with T-Piece 18F/22M/22M + 0.15m Corrugated Tubing + Cap + 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-097LV	Adult Aerosol Face Mask Nose Clip with Large Volume (20ml) Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
MaxiNeb Duo					
032-10-031	MaxiNeb Duo Nebuliser	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-031U	MaxiNeb Duo Nebuliser	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-033	MaxiNeb Duo Nebuliser & Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-033U	MaxiNeb Duo Nebuliser & Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-034	MaxiNeb Duo Nebuliser & Mouthpiece And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-034U	MaxiNeb Duo Nebuliser & Mouthpiece And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-037	MaxiNeb Duo Nebuliser And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-037U	MaxiNeb Duo Nebuliser And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-038	MaxiNeb Duo Nebuliser & Mouthpiece And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-038U	MaxiNeb Duo Nebuliser & Mouthpiece And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-039	MaxiNeb Duo Nebuliser & Mouthpiece, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-039U	MaxiNeb Duo Nebuliser & Mouthpiece, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-046	MaxiNeb Duo Nebuliser With Adult Closed System Mask, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-046U	MaxiNeb Duo Nebuliser With Adult Closed System Mask, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-048	MaxiNeb Duo Nebuliser With Adult Closed System Mask, Tubing, Filter And Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-048U	MaxiNeb Duo Nebuliser With Adult Closed System Mask, Tubing, Filter And Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-082	MaxiNeb Duo Nebuliser With Paediatric Mask And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-082U	MaxiNeb Duo Nebuliser With Paediatric Mask And Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-083	MaxiNeb Duo Nebuliser With Paediatric Closed System Mask, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-083U	MaxiNeb Duo Nebuliser With Paediatric Closed System Mask, Tubing And Filter	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-085	MaxiNeb Duo Nebuliser With Paediatric Closed System Mask, Tubing, Filter And Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-085U	MaxiNeb Duo Nebuliser With Paediatric Closed System Mask, Tubing, Filter And Mouthpiece	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-142	MAXINEB DUO NEBULISER & MOUTHPIECE, TUBING AND PEP CAP	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-143	MAXINEB DUO NEBULISER & MOUTHPIECE, TUBING, FILTER AND PEP CAP	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N

032-10-064	Mouthpiece 22mm	Class IIa (Rule 2)	44545	Breathing mouthpiece, single use	N
010-036	T-Piece for MaxiNeb Nebuliser 22mm F / M / M Connections	Class IIa (Rule 2)	01340	Tubemask, training circuit connector, single-use, non-sterile	N
032-10-065	Mouthpiece 22mm and Nebuliser T-Piece with 22F/22m/22m Connections	Class IIa (Rule 2)	44545	Breathing mouthpiece, single use	N
032-10-120	In-Line T-Piece with Self-Sealing Valve For MaxiNeb Nebuliser	Class IIa (Rule 2)	00057	Non-rebreathing valve, single-use	N
032-10-121	In-Line T-Piece with Self-Sealing Valve with MaxiNeb Nebuliser and 2.1m Oxygen Tubing	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-121/1	MaxiNeb 90 Nebuliser In-Line T-Piece with Self-Sealing Valve Kit 2	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-121/2	MaxiNeb 90 Nebuliser In-Line T-Piece with Self-Sealing Valve Kit 2	Class IIa (Rule 2)	35457	Nebulizing system, non-heated	N
032-10-122	Washington T-Piece with MDI Port	Class IIa (Rule 2)	01346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-021	MaxiNeb Duo Filter Pad	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-021U	MaxiNeb Duo Filter Pad	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-035	MaxiNeb Duo Filter	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-035U	MaxiNeb Duo Filter	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-036	MaxiNeb Duo Filter Master Case	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-036U	MaxiNeb Duo Filter Master Case	Class IIa (Rule 2)	00837	Microbial medical gas filter, single-use	N
032-10-056	Adult MaxiNeb Duo Closed System Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-056U	Adult MaxiNeb Duo Closed System Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-081	Mouth & T-Piece For Vioxine Nebuliser	Class IIa (Rule 2)	01346	Tubemask breathing circuit connector, single-use, non-sterile	N
032-10-086	Paediatric MaxiNeb Duo Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-086U	Paediatric MaxiNeb Duo Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-087	Paediatric MaxiNeb Duo Closed System Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-087U	Paediatric MaxiNeb Duo Closed System Mask	Class IIa (Rule 2)	35142	Rebreathing Aerosol Face Mask, non-sterile	N
032-10-078	MaxiNeb Duo Mouthpiece	Class IIa (Rule 2)	44545	Breathing mouthpiece, single use	N
032-10-078U	MaxiNeb Duo Mouthpiece	Class IIa (Rule 2)	44545	Breathing mouthpiece, single use	N



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030-01-100	Parallel Circuit 2.4m 22mm with Y-Place	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
030-01-105A	Parallel Circuit 3.2m 22mm with Y-Place	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
030-01-106	Parallel Circuit 3.2m 22mm with Y-Place	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
030-01-109K	Parallel Circuit 4.4m 22mm with Y-Place and Low Profile Elbow with Luer Lock Port	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
030-01-105AK	Parallel Circuit 2.4m 22mm with Y-Place Low Profile Elbow with Luer Lock 8/17 Bay	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
030-01-106	Parallel Circuit 2.4m 22mm with Y-Place LP Elbow	Class IIs (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-100	Parallel Circuit 2.4m 22mm with Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105A	Parallel Circuit 3.2m 22mm with Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105A1T	Parallel Circuit 3.2m 22mm with Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105K	Parallel Circuit 2.4m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105L	Parallel Circuit 2.4m 22mm with Y-Piece Low Profile Elbow with Luer Lock Port and Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105M	Parallel Circuit 2.4m 22mm with Y-Piece LP Elbow with Luer BV Filter 1.5m Bag + Catheter Mount	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105N4B	Parallel Circuit 3.2m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105N4B1T	Parallel Circuit 3.2m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105O	Parallel Circuit 3.6m 22mm with Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105O2	Parallel Circuit 4.0m 22mm with Y-Piece 0.8m Limb and 3m Monitoring Line	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105P1	Parallel Circuit 2.4m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105L6	Parallel Circuit 2.4m 22mm with Y-Piece 0.8m Limb and 3m BV Filters & Resa Filter Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105E	Flow-Lock Basic Parallel Basic 3.0M KID	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106	Flow-Lock Parallel Circuit, 1.1m to 3.6m with Swivel Y-Piece 3.0m F/L Kit	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106K	Flow-Lock Parallel Circuit 1.6m HMEF Elbow with Luer Port 0.8m Limb 3m 1.5m F/L Resa Bag Argonite Flow-Lock Parallel Circuit 0.7m to 1.5m with Y-Piece KID Kit	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106A	Flow-Lock Parallel Circuit Y.B/C 3m (X)3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B	Flow-Lock Parallel Swivel Y.B/C 2m (X)2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-105C AUS	Flow-Lock Parallel Swivel Y.B/C 2m (X)2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B6	Flow-Lock Parallel Circuit - 22mm 0.7-2.3m with 22mm F Soft Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106D	Flow-Lock Parallel Circuit - 35mm to 9.0m with Swivel Y-Piece 3.0m F/L Limb and 3m Resa Bag, Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106E AUS	Flow-Lock Parallel Swivel Y.B/C 3M (X)3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106A1A	Flow-Lock Parallel Circuit - 9.7m to 2m Y-Piece 1.6m F/L Limb and Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1T	Flow-Lock Parallel Circuit - 0.7m to 2m Y-Piece with Luer Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1TJ	Flow-Lock Parallel Circuit - 0.7m to 3.0m Y-Piece with Luer Lock Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1TJ1	Flow-Lock Parallel Circuit - 1.1m to 3.0m Y-Piece with Luer Lock Elbow and Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1TJ2	Flow-Lock Parallel Circuit - 0.6m to 1.5m Y-Piece with Luer Lock Elbow and 1.5m Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1TJ3	Flow-Lock Parallel Circuit - 0.75m to 2.0m Y-Piece with Luer Lock Elbow and 1.5m Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-106B1TJ4	Parallel Circuit 1.6m 22mm with Y-Piece and 0.8m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120A	Argonite Parallel Circuit 1.6m 22mm with Y-Piece and 0.8m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120B	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb and Low Profile Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120C40	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120B1	Bifurcated Breathing System 1.6m 22mm	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120B1	Bifurcated Breathing System 2.0m 22mm with 22mm F Soft Connector and 2.4m Limb with 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-120B2	Bifurcated Breathing System 2.2m 1.9m 20mm Silicone Composite Mount 22F Swivel Elbow with Cap	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-100	Basic Parallel 1.8m + HMEF + LEBow + 1.5 Limb + 2m Mask	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110X	Parallel Circuit 2.4m 22mm with Y-Piece 1.8m Limb Low Profile Elbow APL Valve and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110Y	Parallel Circuit 1.6m 22mm with Y-Piece 0.9m Limb Low Profile Elbow APL Valve and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 2.4m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb with Open Out Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 4.5m 22mm with Savelve Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 4.5m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
110LXKAG	Parallel Circuit 2.4m 22mm with Y-Piece 1.5m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LXK	Parallel Circuit 4.5m 22mm with Savelve Y-Piece 2.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
110LXK	Parallel Circuit 4.5m 22mm Custom Kit E	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 1.6m Custom Kit A For GE Anease Aysa and Aspire Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110LX	Parallel Circuit 2.4m Custom Kit B For GE Anease Aysa and Aspire Connectors with ABS	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110701	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb Elbow 3m Monitoring Line and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-115320	Parallel Circuit 4.5m 22mm with Y-Piece 1.5m Limb Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-115320	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb LP Elbow with Luer Port and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-115641B	Argentic Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb LP Elbow with Luer Port and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-115641B	Parallel Circuit 1.6m 22mm with Y-Piece 1.5m Limb Low Profile Elbow with Luer Port and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-115641B	Argentic Parallel Circuit 1.6m 22mm with Y-Piece 1.5m Limb LP Elbow with Luer Port and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1111	Parallel Circuit 2.4m 22mm Y-Piece 0.8m Limb Low Profile Elbow Monitoring Line and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-111701	Parallel Circuit 2.4m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag + 3m Mon Line	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-111E	Parallel Circuit 4.5m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-111J	Parallel Circuit 2m 22mm Y-Piece 1.5m F.Limb LP Elbow B Viral Filter Cath Mount and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11130	Flexi-Lox Parallel Circuit 2m 22mm Y-Piece HMEF C-Mount 1.5m F.Limb 2m M.Limb and 2L Res Bag Mask	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1120	Flexi-Lox Parallel Circuit 2m 22mm Y-Piece HMEF C-Mount 1.5m F.Limb 2m M.Limb and 2L Res Bag Mask S	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-123AG	Argentic Parallel Circuit Adult 2.4m Kit 1	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-196418	Flow-Lox Parallel Circuit - 0.7m to 2.0m Y-Piece 1.5m F.L. Limb and Elbow Mask + Adult HMEF	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-110LX	Parallel Circuit 2.4m with Y-Piece and HMEF Filter + 1.5m Limb + 2L Res Bag with Cath Mount	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-130640	Parallel Circuit 1.6m 22mm with Y-Piece Low Profile Elbow Adult Catheter Mount	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-130640	Parallel Circuit 1.6m 22mm with Detachable Y-Piece Low Profile Elbow Adult HMEF and Catheter Mount	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-0404	Parallel Circuit 3.5m 22mm with Y-Piece	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
550-003-150	Parallel Smoothbore Circuit 1.5m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
550-009-150J	Parallel Smoothbore Circuit 1.5m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11011	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11012	Parallel 1.6m (17") Circuit + Elbow 2L Reservoir Bag + 1.5m Limb	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-119	Breathing Circuit with multipurpose 32M Adult BV Nitir	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N



038-02-103B18	Pediatric Parallel Circuit 1.6m with Y-Piece 1.6m Limb Low Elbow and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110A11	Pediatric Parallel Circuit 15mm 1.6m with 22mm F Connectors and 1.5m Limb 1L Resor Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110A2	Pediatric Parallel Circuit 1.6m with 22mm F Connectors and 1.5m Limb 1L Resor Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110C	Pediatric Parallel Circuit 1.6m with Y-Piece 1.6m Limb Low Profile Elbow and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110C1	Pediatric Circuit 1.6m Single Y-Piece+Collater Mount 15cm+2m Limb+1.4m Limb+1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110D	Pediatric Parallel Circuit 3.2m with Y-Piece 1.6m Limb Low Profile Elbow and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110L	Pediatric Parallel Circuit 2.4m with Ported Y-Piece Elbow with Lear 2.4m Limb and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-111H	Pediatric Parallel Circuit 2.0m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-120	Pediatric Parallel Breathing Circuit 1.6m (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-120 AUS	Pediatric Parallel Breathing Circuit 1.6m (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-120C2	Pediatric Parallel Breathing Circuit 1.6m with Y-Piece Low Elbow Monitoring Line 3L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-123	Pediatric Smoothbore Parallel B/C 1.6m (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-123 AUS	Pediatric Smoothbore Parallel B/C 1.6m (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-155B1	Parallel Smoothbore Circuit 2.0m 22mm+Low Elbow+Flex 22F Connectors+2xValve Traps+1.2m Limb+2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-155B2	Parallel Smoothbore Circuit 2.0m 22mm+Low Elbow+Flex 22F Connectors+2x Valve Traps+1.2m Limb+2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-155U1	Parallel Circuit 1.6m 22mm + Ported Y-Piece + Lear Elbow + 2 x Water Traps + 1.0m Limb + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-155D	Pediatric Parallel Circuit 1.6m with Ported Y-Piece + 2 x Water Traps + 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-163/19C	Pediatric Smoothbore Circuit 1.6m with Y-Piece + Detachable Y-Piece + Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165	Pediatric Parallel Circuit 1.6m with Y-Piece 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165C1	Pediatric Parallel Circuit 1.6m 0.5L Res Bag with T-Piece 1.5m Limb 22mm F and 22mm MM Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165D1	Pediatric Parallel Circuit 2.0m with 2.0m 15mm Tube Limb with 22mm F Connectors and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-165C	Pediatric Breathing System Pack 1.5m 15mm Tubing with Ayres T-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165AG	Argentic Pediatric Parallel Circuit 1.6m with Y-Piece + 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165HUR1	Pediatric Parallel Circuit 1.2m with Y-Piece 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165HUR2	Pediatric Breathing System 1.5m 15mm Y-Piece with Lear Elbow and 1.5m Limb 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165K	Pediatric Parallel Circuit 1.6m with Y-Piece+22mm F and 22M/22M/15F Connector + 1.2m Limb Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165R41	Pediatric Parallel Circuit 1.6m with Y-Piece Low Profile Elbow with 1.5m Limb and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165J	Pediatric Parallel Circuit 2.4m with Y-Piece + 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165I	Pediatric Parallel Circuit 1.0m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165X	Pediatric Parallel Circuit 3.2m with Y-Piece + 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165XL	Pediatric Parallel Circuit 3.2m with Y-Piece + 22mm F Connectors and 22mm MM Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165J21	Pediatric Parallel Circuit 1.6m with Ported Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165G41	Pediatric Parallel Circuit 1.2m with Lear Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165B1	Pediatric Parallel Circuit 1.6m with Lear Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-02-1658108	Paediatric Parallel Circuit 1.5m with 0.8m x 22mm Tube Limb and 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-16581	Paediatric Parallel Circuit 1.5m with Porec Y-Piece and Swivel Elbow	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-4002U	Paediatric Parallel Circuit 48" with Y-Piece LP Elbow Mini BV Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-4002U	Paediatric Parallel Circuit 72" with Y-Piece Luer Elbow Mini BV Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-410U	Paediatric Flexi-Lock Parallel Circuit 78" with Y-Piece Luer Elbow 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-411U	Paediatric Flexi-Lock Parallel Circuit 72" with Y-Piece Luer Elbow 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-412U	Paediatric Flexi-Lock Parallel Circuit 96" Y-Piece Luer Elbow Mini BV Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-5167	Paed Flex Lock Parallel Circuit 2.0m BV Filter Mini HMEF 3m MLimb 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-6202R	Paed Flex-Lock Parallel circuit 2.4m, mini BV, mini-HMEF, elbow with Luer Port 2m W/L Line&STR	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-6299U	Paediatric Parallel Circuit 40" Y-Piece Luer Elbow 1 Bacterial Viral Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-681U	Paediatric Parallel Circuit 40" Y-Piece Luer Elbow 2 x HMEF Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-683U	Paediatric Parallel Circuit 60" Y-Piece Luer Elbow 1 Bacterial Viral Filter 2L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-687U	Paediatric Parallel Circuit 100" Low Dead Space Y-Piece with 1 BV Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-709U	Paediatric Parallel Circuit 96" Y-Piece Luer Elbow 2 x Bacterial Viral Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-713U	Paediatric Parallel Circuit 96" Y-Piece Luer Elbow 2 x Bacterial Viral Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-715U	Paediatric Parallel Circuit 96" Luer Y-Piece Luer Elbow 2 x Bacterial Viral Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-719U	Paediatric Parallel Circuit 72" Y-Piece Luer Elbow 1 Bacterial Viral Filter 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Paediatric Smooth Bore					
038-02-162	Paediatric Smoothbore Parallel Circuit 1.5m with Y-Piece	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-163	Paediatric Smoothbore Parallel Circuit 1.6m with Detachable Y-Piece Kit 2	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1631	Paediatric Smoothbore Parallel Circuit 1.5m Y-Piece Luer Elbow x Flex 22F Connectors 1.2m Limb x 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-184	Paediatric Smoothbore Parallel Circuit 1.5m with Low Dead Space Y-Piece and Monitoring Port Kit 3	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1658168	Paediatric Parallel Circuit 4.0m 15mm with Swivel Y-Piece with Luer Port and 1.2m Limb x 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-166	Paediatric Smoothbore Parallel Circuit 1.6m	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1661	Paediatric Smoothbore Parallel Circuit 3m	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1965U	Paediatric Smoothbore Parallel Circuit 4.0m with Y-Piece 22mm F Connectors and 22mm M/M Connector	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1966C	Paediatric Smoothbore Parallel Circuit 1.5m	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1969C	Paediatric Smoothbore Parallel Circuit 2.4m	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Paediatric Flexi-Lock					
038-02-111U	Paed Flex-Lock Parallel Circuit 2.0m Y-Piece Cath Mount BV Filter 1.5m FIF Limb Face Mask Size 2	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-113U	Paed Flex-Lock Parallel Circuit 2.0m Y-Piece HMEF Cath Mount 1.5m FIF Limb 3m MLimb 1L Res Bag Mask 2	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-180	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.5m with Y-Piece x Elbow x 22mm F Connectors	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-190201A	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.5m Kit 1	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-190F	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.5m Kit 2	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-190U	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.5m Kit 1	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-02-180	Pediatric Flexi-Link Parallel Circuit 0.5m to 1.0m with Y-Piece + Elbow + 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-190K	Pediatric Flexi-Link Parallel Circuit 1.3m+HMEF + Luer Elbow+0.5m 3/4, 22mm Luer3m+3m No Luer+1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1800SA	Pediatric Flexi-Link Basic Parallel Circuit 3.0M Kit 2	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1800R	15mm Flexi-Link 1.5m +HMEF + L Elbow + 1.5m L + 2m ML + 1L Res	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004A	Pediatric Flexi-Link Parallel Circuit - 0.55m to 1.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004J	Pediatric Flexi-Link Parallel Circuit - 0.55m to 1.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004J7	Pediatric Flexi-Link Parallel Circuit - 0.55m to 1.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004K	Pediatric Flexi-Link Parallel Circuit 0.5m to 1.4m with Y-Piece + Elbow + 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004N	Pediatric Flexi-Link Parallel Circuit - 0.55m to 2.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004N1	Pediatric Flexi-Link Parallel Circuit - 0.55m to 2.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18004N17	Pediatric Flexi-Link Parallel Circuit - 0.5m to 2.0m Y-Piece with Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18111	Pediatric Flexi-Link Parallel Circuit - 1.1m to 3.0mm Y-Piece + Luer Elbow and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1812	Pediatric Flexi-Link Parallel Circuit 0.5-1.5m 15mm with Y-Piece Luer Elbow and 1.5m Lumb 15mm	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18124	Pediatric Flexi-Link Parallel Circuit 0.5-1.5m 15mm with 1.5m Smoothbore Limb and 1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-18125	Pediatric Flexi-Link Parallel Circuit 15mm 0.5-1.0m with 1 Connected Limb and 1.5m Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1816	Pediatric Flexi-Link Parallel Circuit 1.5m 15mm 2.0m Smoothbore Limb and 1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1817	Pediatric Flexi-Link Parallel Circuit 2.0m 15mm with 2.0m Smoothbore Limb and 1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-185	Pediatric Flexi-Link Parallel Circuit 1-1.3.0m + Swivel Luer Y-Piece + 2xWater Traps + 1.2m Lumb +1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-300	Pediatric F2 Connectors 1.5m 15mm 2.0m Smoothbore Limb 15mm and 1L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-400S1	Pediatric Flexi-Link Parallel Circuit 400 with Y-Piece Luer Elbow 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-400R	Pediatric Flexi-Link Parallel Circuit 400 with Y-Piece Luer Elbow Mini BV Filter 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-421U	Pediatric Flexi-Link Parallel Circuit 72" with Y-Piece Luer Elbow Mini Filter 20mm 20mm 20mm 20mm	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-425S	Pediatric Flexi-Link Parallel Circuit 72" with Y-Piece Mini BV Filter 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-427U	Pediatric Flexi-Link Parallel Circuit 100" with Y-Piece Luer Elbow Mini BV Filter 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-445U	Pediatric Flexi-Link Parallel Circuit 400 with Y-Piece Luer Elbow Mini BV Filter 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-454U	Pediatric Flexi-Link Parallel Circuit 400 with Y-Piece Luer Elbow Mini BV Filter 1/4 L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Neonatal Parallel Circuits					
038-03-1101	Neonatal Parallel Circuit 1.5m 10mm Y-Piece with Suction Valve and 15mm	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-1108	Neonatal Parallel Circuit 1.6m 10mm Y-Piece with Suction Valve + 22mm F Connectors + 1.0m Lumb 0.5L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-1162	Neonatal Parallel Circuit 4.0m 10mm Y-Piece with Suction Valve and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-11001	Neonatal Parallel Circuit 1.6m 10mm Y-Piece with Suction Valve and 22mm F Connectors	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-11003S	Parallel Neonatal 1.6m (63") Anaesthetic Circuit	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Neonatal Smoothbore Circuits					
038-03-104T1	Neonatal Smoothbore Circuit 1.5m 10mm with Flexible 22mm F Connectors + 1.5m Lumb + 0.5L Res Bag	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-102	Neonatal Parallel Smoothbore Circuit 1.2m 10mm with Flexible 22P Conns + 1.2m Lumb + 0.5L Res	Class Iia (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-03-125	Neonatal Smoothbore Circuit 1.2m 16mm+Luer Elbow+Flexible 22F Connectors+1.2m Limb with 1L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-130	Neonatal Smoothbore Circuit 2.5m 16mm with 2 x Water Traps and 1.2m Limb + 0.5L Res Bag	Class IIIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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Parallel Circuits - Anaesthesia Breathing Systems (Sterile)

TF: 056a

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO₂) absorber, and a monitor. It typically includes both an inhalation and exhalation route and consists of breathing hoses, a ventilation and/or reservoir bag(s), a Y-piece, connectors/adaptors, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
Adult Basic Parallel					
038-01-100355STR	Parallel Circuit 1.6m 22mm with Y-Piece and Thermoshield HMEF with CO ₂ Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-100640STR	Parallel Circuit 1.6m 22mm with Y-Piece and Low Profile Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1006401STR	Parallel Circuit 1.6m 22mm with Y-Piece and Elbow Large HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1006402STR	Parallel Circuit 1.6m 22mm with Y-Piece and Elbow Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10215STR	Parallel Circuit 1.6m 22mm with Swivel Y-Piece Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1006415STR	Parallel Circuit 1.6m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10635STR	Flexi-Lock Parallel Circuit - 0.7m to 2.0m with Y-Piece & HMEF (Sterile)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-122F5STR	Parallel Circuit 3.0m 22mm Swivel Y-Piece Luer Elbow & 3.0m Limb and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-122H5STR	Parallel Circuit 1.8m 22mm Swivel Y-Piece 1.8m Blue Limb LP Elbow with Luer and 2L Res Bag Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1003STR	Parallel Circuit 1.6m 22mm with Y-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1103STR	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb Low Profile Elbow and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110KS	Parallel Circuit 1.6m 22mm with Y-Piece 1.2m Limb LP/Elbow + HMEF + 3L Res Bag 3m Non Line Sterile	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-110359S	Parallel Circuit 1.6m 0.8m Limb LP Elbow HMEF 2L Res Bag + F.L. Catheter Mount with Swivel Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1106415STR	Parallel Circuit 1.6m 22mm with Y-Piece 0.8m Limb LP Elbow with Luer Port and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-1205STR	Parallel Circuit 1.6m 22mm with Y-Piece and 0.8m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Flexi-Lock Circuits					
038-01-100P365STR	Flexi-Lock Parallel Circuit - 0.7m to 2.0m with 1.5m Flexi-Lock Limb and SV Filter	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11643STR	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11618STR	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11655STR	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11665STR	Flexi-Lock Parallel Circuit - 0.8m to 1.5m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11675STR	Flexi-Lock Parallel Circuit - 0.8m to 1.5m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11685STR	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11695STR	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11695STR	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-8145STR	Adult Exp Circuit 95° Y-Piece Luer Elbow Bacterial Viral Filter Mask 3L Res Bag & M/Line (Sterile)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-451	Adult Hygrovent Gold WFL Breathing System 2.4m Kit 1	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
Adult Smooth Bore					
038-01-1045STR	Smoothbore Circuit 1.6m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10451STR	Smoothbore Circuit 1.6m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10415STR	Smoothbore Circuit 1.6m 22mm with Y-Piece with Elbow and 3L Reservoir Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10435STR	Smoothbore Circuit 3.0m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-104X5STR	Smoothbore Circuit 1.6m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-104D5STR	Smoothbore Circuit 1.6m 22mm Y-Piece 1.6m Limb Low Profile Elbow with 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10425STR	Smoothbore Circuit 1.2m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10445STR	Smoothbore Circuit 2.1m 22mm with Flexible 22mm F Connectors and 2.1m Smoothbore Limb and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10455STR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF Luer and Smoothbore Catheter Mount DSE with 22F Conn	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10465STR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF w/o Luer & Smoothbore Catheter Mount DSE with 15M Conn	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10475STR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF Luer and Smoothbore Catheter Mount DSE with 22F Conn	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10485STR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF w/o Luer & Smoothbore Catheter Mount DSE with 22F Conn	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1075STR	Smoothbore Circuit 2.1m 22mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-155843STR	Smoothbore Circuit 2.4m 22mm + HME Filter + 3.5m Monitoring Line + Swivel Elbow Catheter Mount 15cm	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-16633STR	Smoothbore Circuit 3.0m 15mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-16645STR	Smoothbore Circuit 4.0m 15mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
550-431-150J	Smoothbore Circuit 1.5m 22mm-Hygrovent 3 HMEF+Flexi-Lock Swivel Cath Mount+Flexible 22F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Pediatric Basic Parallel					
038-02-165615STR	Pediatric Parallel Circuit 1.6m with Luer Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1105STR	Pediatric Parallel Circuit 1.6m with Y-Piece 0.8m Limb Low Profile Elbow and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110615STR	Pediatric Parallel Circuit 1.6m with Y-Piece 0.8m Limb Elbow with Luer Port and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165357S	Pediatric Parallel Circuit 1.6m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165366S	Pediatric Parallel Circuit 1.5m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165810357S	Pediatric Parallel Circuit 1.6m Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-02-16591055STR	Pediatric Parallel Circuit 1.6m with 0.8m x 22mm Tube Limb and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165015STR	Pediatric Parallel Circuit 2.0m with 2.0m 15mm Tube Limb with 22mm F Connectors and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-166025STR	Pediatric Parallel Circuit 2.0m with 2.0m 15mm Tube Limb with 22mm F Connectors and 0.5L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-11045STR	Pediatric Parallel Circuit 1.6m with Y-Piece 0.8m Limb Low Profile Elbow and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Pediatric Flexi-Lock Circuits					
038-02-180KSA	Pediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-180KSB	Pediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 6	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-160K3	Pediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Pediatric Smooth Bore					
038-02-1665STR	Pediatric Smoothbore Circuit 1.6m 15mm with Y-Piece and Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-166C3TR	Pediatric Smoothbore Circuit 1.8m 15mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Neonatal Smooth Bore					
038-02-1045STR	Neonatal Smoothbore Circuit 1.5m 10mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Corrugated Circuits					
038-04-450	Adult Hygrovent Gold WFL Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N



Mapleson Circuits - Anaesthesia Breathing Systems (Sterile and Non-Sterile) TF: 056a

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO₂) absorber, and a monitor. It typically includes both an inhalation and exhalation route and consists of breathing tubes, a ventilation and/or reservoir bag(s), a Y-piece, connectors/adaptors, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
Adult Mapleson Circuits					
020-195A	Mapleson F Ayres T-Piece Custom Kit A	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-251B	Mapleson D Adult Bain System 1.6m 22mm with 2L Res Bag APL Valve and 1.6m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-251C	Mapleson D Adult Bain System 1.6m 2L Res Bag APL Valve 1.6m Limb 6mm M22mm F Adaptor O2 Tubing	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-255/1	Mapleson C Adult Bagging System 1.6m 10mm T-Piece + Luer Elbow + Fixed APL 15F/6-9mm F Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-256	Mapleson A Adult Magill System 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-258Ag	Argentic Mapleson A Adult Magill System 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-257	Mapleson A Adult Parallel Lack 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-257Ag	Argentic Mapleson A Adult Parallel Lack 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-258B	Mapleson C Adult Bagging System 1.6m with Star Lumen Tube and 6mm M to 22mm F Adaptor	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-255	Mapleson C Adult Bagging System 1.6m 10mm Tubing with 2L Res Bag + APL Valve + 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-255D	Mapleson C Adult Bagging System 2.1m 10mm Tubing with 2L Res Bag + APL Valve + 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-258	Mapleson C Adult Bagging System 4m Star Lumen Tube with 2L Res Bag + APL Valve and 22mm F Adaptor	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-258A	Mapleson C Adult Bagging System 4m Star Lumen Tube with 2L Res Bag + APL Valve and 22mm F Adaptor	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-251	Mapleson D Adult Bain System 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-251Ag	Argentic Mapleson D Adult Bain System 1.6m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-253	Mapleson D Adult Bain System 2.4m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-254	Mapleson D Adult Bain System 5.4m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-254Ag	Argentic Mapleson D Adult Bain System 5.4m 22mm with 2L Res Bag and APL Valve	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-01-209	Bain Coaxial System 1.6m 22mm with 22mm M Swivel Connector and Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-209U	Bain Coaxial System 1.6m 22mm with 22mm M Swivel Connector and Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-209B	Bain Coaxial System 1.6m 22mm Custom Kit B	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-209BAG	Argentic Bain Coaxial System 1.6m 22mm Lightweight Tube Custom Kit B	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-210	Bain Coaxial System 2.4m 22mm with 22mm M Swivel Connector and Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-210Ag	Argentic Bain Coaxial System 2.4m 22mm Custom Kit A	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-201	Bain Coaxial System 1.6m 22mm Custom Kit A	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-201Ag	Argentic Bain Coaxial System 1.6m 22mm Custom Kit A	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-251/441	Mapleson D Adult Bain System 1.6m with 2L Res Bag + APL Valve + L.P. Elbow with Luer Lock Port	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-255E	Mapleson C Adult Bagging System 3.2m 10mm Tubing with 2L Res Bag + APL Valve + 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-258STR	Mapleson C Adult Bagging System 1.6m with Star Lumen Tube and 6mm M to 22mm F Adaptor	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-100	Mapleson A Adult Parallel Lack 4.5m 22mm Tubing	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Pediatric Mapleson Circuits					
038-02-191A	Mapleson F Infant T-Piece 2.4m 10mm Corrugated Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-191T	INFANT T-PIECE (10MM CORR OG TUBE)-MAPLESON F + T TAP RES BAG	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-192	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-192U	Jackson Rees (1/2 Ltr Res Bag 7F1 Fresh Gas Tube)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-193	Mapleson F Ayres T-Piece 2.4m 10mm Corrugated Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-193U	Jackson Rees (1 Ltr Res Bag 7F1 Fresh Gas Tube)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-195A	Mapleson F Ayres T-Piece 4.0m Star Lumen Inspiratory Tube Kit 15	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-195B	Mapleson F Ayres T-Piece 1.6m Star Lumen Inspiratory Tube Kit 9	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-195C	Mapleson F Ayres T-Piece - 2.1m Star Lumen Inspiratory Tube Kit 12	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196G41	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196C1	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube and 1L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196H	Mapleson F Ayres T-Piece 3.2m 10mm Corrugated Inspiratory Tube Kit 8	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-02-199M	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196A	Mapleson F Ayres T-Piece 2.4m 10mm Corrugated Inspiratory Tube Kit 7	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196B	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196F	Mapleson F Ayres T-Piece 10mm Corrugated Inspiratory Tube Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196G	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196J	Ayres T-Piece (2.1m 10mm Corrugated O2 Tube) + 640 Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196L	Mapleson F Ayres T-Piece 3.2m 10mm Corrugated Inspiratory Tube Kit 6	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196N	Mapleson F Ayres T-Piece Kit 8	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-197	Jackson Rees (2 Ltr Res Bag 7F1 Fresh Gas Tube) Paed	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-197U	Jackson Rees (2 Ltr Res Bag 7F1 Fresh Gas Tube) Paed	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-270	Mapleson C Paediatric Direct System 1.6m 10mm with 1L Res Bag APL and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-270C	Mapleson C Paediatric Direct System 3.0m 10mm with 1L Res Bag APL and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-271	Mapleson C Paediatric Bagging System 1.6m 10mm with 0.5L Res Bag APL Valve and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-271U	Mapleson C Paediatric Bagging System 1.6m 10mm with 0.5L Res Bag APL Valve and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-272	Mapleson C Paediatric Direct System 1.6m 10mm with 1L Res Bag APL Valve and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-272U	Mapleson C Paediatric Direct System 1.6m 10mm with 1L Res Bag APL Valve and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-272CAU	Mapleson C Paediatric Bagging System 1.6m 10mm with 1L Res Bag APL Valve and 15F/6-9mm F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-273	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-273D	Corrugated Tube 4.0m 15mm with Paediatric APL Valve and 0.5L Res Bag to fit Mapleson F Ayres T-Piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-273E	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 6	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-191	Mapleson F Infant T-Piece 1.6m 10mm Corrugated Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-191AUS	Infant T-Piece (10mm Corrugated O2 Tube) Mapleson F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-191STR	Mapleson F Infant T-Piece 2.1m Star Lumen Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1963TR	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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038-02-198	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-196C	Mapleson F Ayres T-Piece 1.6m 10mm Corrugated Inspiratory Tube Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-198LNRH	Mapleson F Ayres T-Piece 12m 10mm Corrugated Inspiratory Tube Kit 10	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-199	Mapleson F Infant T-Piece 2.1m Star Lumen Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-199A	Mapleson F Infant T-Piece 2.1m Star Lumen Inspiratory Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-195	Mapleson F Ayres T-Piece 2.1m Star Lumen Inspiratory Tube Kit 11	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-198	Mapleson F Ayres T-Piece 2.1m Star Lumen Inspiratory Tube Kit 13	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-198D	Mapleson F Ayres T-Piece 2.1m Star Lumen Inspiratory Tube Kit 14	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-198/22	Ayres T-Piece Custom Built With T-Tap 1l Bag 22mm Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-198/22	Ayres T-Piece Custom Built With T-Tap 0.5l Bag 22mm Tube	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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Nitrous Oxide Breathing Systems (Non-Sterile)

TF: 056a

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 humidity, 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	MDN CODE	MDN TERM	ROHS APPLIES Y/N
038-01-173	Oxygen / Nitrous Oxide Circuit 2.4m 22mm Tube One Way Valve Detachable Scavenging Tube 22mm F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-173A1	Oxygen/N2O Circuit 2.4m(22mm) Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-174	Oxygen / Nitrous Oxide Circuit 1.5m with Mouthpiece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-176	Oxygen / Nitrous Oxide Circuit 2.4m 22mm Tube with Mouthpiece One Way Valve and 22mm F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-176A	Oxygen / Nitrous Oxide Circuit 2.8m with Mouthpiece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-176AC	Oxygen / Nitrous Oxide Circuit 2.4m with Mouthpiece and BV Filter	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-177	Oxygen / Nitrous Oxide Circuit 2.4m 22mm Tube with Face Mask One Way Valve and 22mm F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-178	Oxygen / Nitrous Oxide Circuit 2.4m 22mm Tube with Mouthpiece Face Mask One Way Valve and 22mm F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-182	Oxygen / Nitrous Oxide Circuit 2m F.I. Tube with Scavenging Limb with 19mm Connector and V Filter	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-259Q	Macpac Kit with 10 x Macpac Kit and 150 x BV Filter and 1x 10m Scavenger Tube with 30F Connector	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-170SP	Oxygen / Nitrous Oxide T-Piece Circuit with Filters	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

Neonatal Breathing Systems - Anaesthesia (Sterile & non-sterile)

TF: 056a

Intended use: Sterile & non-sterile 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 humidity, 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	MDN CODE	MDN TERM	ROHS APPLIES Y/N
038-03-110	Neonatal Parallel 1.6m W/Elbow 0.5 Res/Bag + 0.5m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-110STR	Neonatal Parallel 1.6m W/Elbow 0.5 Res/Bag + 0.5m Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-03-314	Neonatal Parallel Breathing System 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

Air Liquide Medical Systems – Anaesthesia Breathing Systems (Non-sterile, single use)

TF: 056a

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO₂) absorber, and a monitor. It typically includes both an inhalation and exhalation route and consists of breathing tubes, a ventilation and/or reservoir bag(s), a Y-piece, connectors/adaptors, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	MDN CODE	MDN TERM	ROHS APPLIES Y/N
038-01-104M	Smoothbore Circuit 1.6m 22mm Tube with Y-Piece - (Ref K920100)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-168 ALMS	Paediatric Smoothbore Parallel Circuit 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-288	Oxiris Circuit 1.6m with Exhalation Valve - K9202000	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N



Anaesthesia Breathing Systems (Non-Sterile)

TF: 056a

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO₂) absorber, and a monitor. It typically includes both an inhalation and exhalation route and consists of breathing tubes, a ventilation and/or reservoir bag(s), a Y-piece, connectors/adaptors, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	MDN CODE	MDN TERM	ROHS APPLIES Y/N
038-01-500	Ventiflow Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500A	Ventiflow Basic Coaxial Circuit 1.6m with Hygrovent S HMEF and Luer Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500AG	Argentic Ventiflow Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500A1	Ventiflow Basic Coaxial Circuit 1.6m with Hygrovent S HMEF and Luer Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500A2	Ventiflow Basic Coaxial Circuit 1.6m with Hygrovent S HMEF+Cash Mount 20cm with Portel Swivel Elbow 22F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500A3	Ventiflow Basic Coaxial Circuit 1.6m with Hygrovent S HMEF + Flexi-Lock Straight Catheter Mount 15M	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500A4	Ventiflow Basic Coaxial Circuit 1.6m with Hygrovent S HMEF and Smoothbore Catheter Mount 15cm 22F	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500B	Ventiflow Basic Coaxial Circuit 1.6m + HME Filter + Booster T-Piece + Smoothbore Catheter Mount 20cm	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500K	Ventiflow Basic Coaxial Circuit 1.6m with HMEF + Elbow with Luer Port + F.I. 0.5m Limb + 3m Monitoring Line and 1.5m Smoothbore Limb 22mm and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500S	Ventiflow Basic Coaxial Circuit 2.4m W/Flexi-Lock Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500SA	Argentic Ventiflow Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-500SK	Ventiflow Coaxial Circuit 2.4m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501	Ventiflow Basic Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501AUS	Ventiflow Coaxial Breathing System 1.8M (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501L	Ventiflow Basic Coaxial Circuit 3.0m Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501S	Ventiflow Basic Coaxial Circuit 1.6m Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501AG	Argentic Ventiflow Basic Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501A4	Ventiflow Basic Coaxial Circuit 1.6m Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501HAG	Argentic Ventiflow Basic Coaxial Circuit 1.6m with 1.5m Argentic Limb Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501S16	Ventiflow Basic Coaxial Circuit 1.6m 5m Monitoring Line Acid HMEF 3m Limb with APL Valve 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501S17	Ventiflow Basic Coaxial Circuit 1.6m with Luer Elbow and 0.5-1.2m Flexi-Lock Limb 22mm + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-501S18	Ventiflow Basic Coaxial Circuit 1.6m with Luer Elbow and 1.5m Smoothbore Limb 22mm and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-502	Ventiflow Basic Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506	Ventiflow Basic Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506AUS	Ventiflow 2.4m Circ 1.8M Blue Refresh Limb 2L	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506AG	Argentic Ventiflow Basic Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506K	Ventiflow Basic Coaxial Circuit 2.4m Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-506L	Ventiflow Basic Coaxial Circuit 2.4m with Luer Elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506S	Ventiflow Basic Coaxial Circuit 2.4m Kit 5	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506A4	Ventiflow Basic Coaxial Circuit 2.4m Kit 4	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506HAG	Ventiflow Basic Coaxial Circuit 2.4m with Luer Elbow and 0.8-2.2m Flexi-Lock Limb 22mm + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-506H1	Ventiflow Basic Coaxial Circuit 3.0m with Luer Elbow and 1.5m Smoothbore Limb 22mm and 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510	Ventiflow Basic Coaxial Circuit 1.6m System with Monitoring Line & Flexi-Lock Limb	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510AUS	Ventiflow 3rd Coaxial Breathing System 1.8M (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510AG	Argentic Ventiflow Standard Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510H1	Ventiflow Standard Coaxial Circuit 1.6m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510STR	Ventiflow Standard Coaxial Circuit 1.6m with Low Profile Elbow and 1.5m Corrugated Limb + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510S1	Ventiflow Standard Coaxial Circuit 1.6m with Low Profile Elbow and 1.5m Corrugated Limb + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510S2	Ventiflow Standard Coaxial Circuit 1.6m with Low Profile Elbow and 1.5m Corrugated Limb + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510S3	Ventiflow Standard Coaxial Circuit 1.6m + 1.5m Corrugated Limb + 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-510S4	Ventiflow Standard Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515	Ventiflow Standard Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515AG	Argentic Ventiflow Standard Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515S	Ventiflow Standard Coaxial Circuit 2.4m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515L	Ventiflow Standard Coaxial Circuit 2.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515N	Ventiflow 3rd Coaxial Breathing System 2.4m (Kit 3)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515S1	Ventiflow 3rd Coaxial Breathing System 2.4m (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515S1AUS	Ventiflow 3rd Coaxial Breathing System 2.4M (Kit 1)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515S2	Ventiflow 3rd Coaxial Breathing System 2.7m (Kit 2)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515S2AUS	Ventiflow 3rd Coaxial Breathing System 2.7m (Kit 2)	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-515STR	Ventiflow Standard Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-517	Ventiflow Basic Coaxial Circuit 3.0m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-517A	Ventiflow Standard Coaxial Circuit 3.0m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-517S1	Ventiflow Basic Coaxial Circuit 3.0m with HME Filter and Smoothbore Ported Elbow Catheter Mount 20cm	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-517S2	Ventiflow Standard Coaxial Circuit 3.0m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-520	Ventiflow Plus Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-520AG	Argentic Ventiflow Plus Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-525	Ventiflow Plus Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-525AG	Argentic Ventiflow Plus Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-530	Ventiflow Max Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-530AG	Argentic Ventiflow Max Coaxial Circuit 1.6m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-535	Ventiflow Max Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-535ag	Argentic Ventiflow Max Coaxial Circuit 2.4m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-713U	Ventiflow Basic Coaxial Circuit 90° Luer Elbow Bacterial Viral Filter with 3L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-715U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow Bacterial Viral Filter with 3L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-751U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow HME Filter 3L Res Bag Size 4 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-752U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 2x BV Filter 3L Res Bag Size 4 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-753U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow Bacterial Viral Filter 3L Res Bag Size 4 Mask	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-754U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 2 x BV Filter 1 HMEF 3L Res Bag Size 4 Mask	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-755U	Ventiflow Coaxial Circuit 72° Plain Elbow 2x BV Filter 1 HMEF 3L Bag Size 5 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-843U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow HMEF 3L Res Bag Size 4 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-850U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 2 x Bacterial Viral Filter 3L Res Bag 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-853U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 1 BV Filter 3L Res Bag Size 4 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-855U	Ventiflow Basic Coaxial Circuit 180° Luer Elbow 1 BV Filter 3L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-856U	Ventiflow Basic Coaxial Circuit 180° Luer Elbow 1 BV Filter 2L Res Bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-858U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 1 BV Filter 3L Res Bag Size 4 Mask 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-859U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 1 BV Filter 2L Res Bag 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-860U	Ventiflow Basic Coaxial Circuit 72° Luer Elbow 1 BV Filter 3L Res Bag 10L MLine	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-862U	Ventiflow Circuit 100° With CO2 Monitoring Line 2L Reservoir Bag BV Filter And Adult Face Mask	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N



Split Lumen Breathing Systems (Non-Sterile)

TF: 056a

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO₂) absorber, and a monitor. It typically includes both an inhalation and exhalation route and consists of breathing tubes, a ventilation and/or reservoir bag(s), a Y-piece, connector/adaptors, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDS CODE	GMDS TERM	ROHS APPLIES Y/N
038-01-900	Intello Plus Adult Kit 1 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-901	Intello Plus Adult Kit 1 - 1.5 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-902	Intello Plus Adult Kit 1.8m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-902/1	Intello Plus Adult Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-903	Intello Plus Adult 2.7m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-903/1	Intello Plus Adult Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-904	Intello Plus Adult Kit 2 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-905	Intello Plus Adult Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-908	Intello Plus Adult Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-908/1	Intello Plus Adult Kit 3 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-907	Intello Plus Adult Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-907/1	Intello Plus Adult Kit 3 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-910	Intello Standard Adult Kit 1 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-911	Intello Standard Adult Kit 1 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-912	Intello Standard Adult Kit 1 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-913	Intello Standard Adult 2.7m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-914	Intello Standard Adult Kit 2 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-914J	Intello Standard Kit 2 - 1.0m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-915	Intello Standard Adult Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-915J	Intello Standard Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-916	Intello Standard Adult Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-916J	Intello Standard Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-917	Intello Standard Adult Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-917J	Intello Standard Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-920	Intello Basic Adult / Paediatric Kit 1 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-920J	Intello Kit 1 - 1.0m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-921	Intello Basic Adult / Paediatric Kit 1 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-921J	Intello Kit 1 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-922	Intello Basic Adult / Paediatric Kit 1 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-922J	Intello Kit 1 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-923	Intello Basic Adult / Paediatric 2.7m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-923J	Intello Kit 1 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-950	Intello Plus Adult Kit 3 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-951	Intello Plus Adult Kit 3 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-952	Intello Plus Adult Kit 3 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-952/1	Intello Plus Adult Kit 3 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-952/2	Intello Plus Adult Kit 4 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-952/3	Intello Plus Adult Kit 5 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-953	Intello Plus Adult Kit 3 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-953/1	Intello Plus Adult Kit 3 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-953/2	Intello Plus Adult Kit 4 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-954	Intello Plus Adult Kit 4 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-955	Intello Plus Adult Kit 4 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-956	Intello Plus Adult Kit 4 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-956/1	Intello Plus Adult Kit 5 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-957	Intello Plus Adult Kit 4 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-957/1	Intello Plus Adult Kit 5 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-958/1	Intello Plus Circuit 2.4m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-959/1	Intello Plus Circuit 3m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-960	Intello Standard Adult Kit 3 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-961	Intello Standard Adult Kit 3 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-962	Intello Standard Adult Kit 3 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-962/2	Intello Plus Adult Kit 4 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-963	Intello Standard Adult Kit 3 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-963/1	Intello Standard Adult Kit 4 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-965	Intello Standard Adult Kit 4 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-965/1	Intello Standard Adult Kit 4 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-966	Intello Standard Adult Kit 4 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-966/1	Intello Standard Adult Kit 4 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-967	Intello Standard Adult Kit 4 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-967/1	Intello Standard Kit 4 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-970	Intello Basic Adult / Paediatric Kit 2 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-970J	Intello Basic Adult / Paediatric Kit 2 - 1.0m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-971	Intello Basic Adult / Paediatric Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-971J	Intello Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-972	Intello Basic Adult / Paediatric Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-972/1	Intello Basic Adult / Paediatric Kit 2 - 1.8m Sterile	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-972J	Intello Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-973	Intello Basic Adult / Paediatric Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-973J	Intello Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-900	Intello Plus Paediatric Kit 1 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-901	Intello Plus Paediatric Kit 1 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-902	Intello Plus Paediatric Kit 1 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-902/1	Intello Plus Paediatric Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-903	Intello Plus Paediatric Kit 1 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-903/1	Intello Plus Paediatric 2.7m Kit 1	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-910	Intello Standard Paediatric Kit 1 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-911	Intello Standard Paediatric Kit 1 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-912	Intello Standard Paediatric Kit 1 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-912/1	Intello Standard Paediatric Kit 1 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-913	Intello Standard Paediatric Kit 2 - 1.8m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-913/1	Intello Standard Paediatric Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-950	Intello Plus Paediatric Kit 2 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-951	Intello Plus Paediatric Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-952	Intello Plus Paediatric 1.8m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-952/1	Intello Plus Paediatric 1.8m Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-953	Intello Plus Paediatric 2.7m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-953/1	Intello Plus Paediatric 2.7m Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-950	Intello Standard Paediatric Kit 2 - 1.0 m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-961	Intello Standard Paediatric Kit 2 - 1.5m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-962	Intello Standard Paediatric 1.8m Kit 2	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-962/1	Intello Standard Paediatric 1.8m Kit 3	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-963	Intello Standard Paediatric Kit 2 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-963/1	Intello Standard Paediatric Kit 3 - 2.7m	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-902/2	Intello Plus Breathing Circuit 1.8m, LL elbow with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-908	Intello Basic Breathing Circuit 3m with LL elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-908/1	Intello Plus Breathing Circuit 3m, LL elbow with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-909	Intello Basic Breathing Circuit 2.4m, LL elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-909/1	Intello Plus Breathing Circuit 2.4m, LL elbow with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-922	Intello Basic Breathing Circuit 1.8m with LL elbow	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

EC Declaration of Conformity



EC Declaration of Conformity



038-01-952/3 DUT	Intello Basic Breathing Circuit 1.8m with internal sampling line	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N
038-01-958 DUT	Intello Basic Breathing Circuit 2.4m with internal sampling line	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N
038-01-958/1 DUT	Intello Plus Breathing Circuit 2.4m, internal sampling line with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N
038-01-959 DUT	Intello Basic Breathing Circuit 3m with internal sampling line	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N
038-01-959/1 DUT	Intello Plus Breathing Circuit 3m, internal sampling line with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N
038-01-962/2 DUT	Intello Plus Breathing Circuit 1.8m, internal sampling line with 1.2m limb and 2L res bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single- use	N

Neonatal Breathing Systems - Ventilator (Sterile & non-sterile)

TF: 056b

Intended use: Non-sterile 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
038-03-315	Neonatal Cold Humidification System	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-315AG	Argentic Neonatal Cold Humidification System	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-190	Neonatal Nitric Oxide Circuit 0.45m 10mm with B/V Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Air Liquide Medical Systems – Ventilator Breathing Systems (Non-sterile, single use)

TF: 056b

Intended use: A non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient, typically connecting the patient, a ventilator/ventilation bag, carbon dioxide (CO2) absorber, and a monitor. It typically includes both an inspiration and exhalation route and consists of breathing tubes, a ventilation and/or reservoir bag(s), a Y-piece, connectors/adapters, and gas sampling ports. The absorber, a one-way directional valve, and adjustable pressure limiting (APL) valve are also devices typically employed in the circuit but may not be a part of this device. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-35-296	Adult Smoothbore Bu-PAP Breathing System 1.5m with Exhalation Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-323B	ALPHA 200 Nebulising IPPB Breathing System 1.0 m Separate Exhalation Valve and New Line + Mouthpiece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-323A	Alpha 200 IPPB Breathing System 1.0m with Exhalation Valve and Mouthpiece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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CPAP Masks (Non-Sterile)

TF: 056b

Intended use: A non-sterile, flexible, form-shaped device designed to be placed over a user's nose and mouth to interface with a continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) unit to provide the respiratory tract with direct ambient air, or medical oxygen (O2) and air, at a higher pressure than ambient air for non-invasive positive pressure ventilation (NPPV). It is typically made of polysilicone materials that create an airtight seal around the nose and mouth. It is available in various designs and sizes and stabilized with a head strap. This is a single-patient device that may be reapplied to the patient over a short term (single-use) before being discarded.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-35-930	Adult CPAP Mask Large	Class Ila (Rule 2)	57813	CPAP/Bi-PAP Face Mask, Single-use	N
038-35-931	Adult CPAP Mask Medium	Class Ila (Rule 2)	57813	CPAP/Bi-PAP Face Mask, Single-use	N

Ventilator Breathing Systems Adult Standard Non-Heated (Non-Sterile)

TF: 056b

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
038-01-130	Ventilator Breathing System Adult 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-130AG	Argentic Ventilator Breathing System Adult 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-130D	Ventilator Breathing System Adult 1.6m with Detachable Inspiratory Limb Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-130F	Ventilator Breathing System Adult 1.6m with In-Line Valve and Maxineb Nebuliser Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-132	Ventilator Breathing System Adult 2.4m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-135	Ventilator Breathing System Adult 1.5m with 0.8m Limb Kit 5	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-140	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports and 1 x Water Trap Kit 6	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-140G41	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports and Elbow with Luer Port Kit 7	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-150	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports and 1 x Water Trap Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-150G41	Ventilator Breathing System Adult 1.6m Y-Piece with 2 Ports LP Luer Elbow + 1 x Water Trap Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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038-01-150B	Smoothbore Parallel Circuit Adult 1.6m Y-Piece with 2 x Ports and 1 x Water Trap Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports and 2 x Water Traps Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155K	Ventilator Breathing System Adult 1.6m 2 x Water Traps 3 x HMEF & Catheter Mount Kit 9	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/12	Ventilator B/Dys 1.6M W/Ports 2 X Traps Insp Limb 1-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/13	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x Maxineb 1 x HMEF Catheter Mount Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/14	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x HMEF & 1 x BV Filter Cath Mount Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/15	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x Heme & 1 x BV Filters Cath Mount Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/15 IN	Ventilator Breathing System Adult 1.6m 2 X Water Traps 1 x Heme & 1 x BV Filters Cath Mount Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155F	Ventilator Breathing System Adult 1.6m Y-Piece with 2xPorts 2xWater Traps + Maxineb Nebuliser Kit 7	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155F/641	Ventilator Breathing System Adult 1.6m LP Luer Elbow 2 x Water Traps + Maxineb Nebuliser Kit 8	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/376B	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports 2 x Water Traps BV Filter-Cath Mount Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/355/306	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports DS Elbow + 2 x W/Traps Adult HMEF + C-Mount	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/355/306 IN	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports DS Elbow + 2 x W/Traps Adult HMEF + C-Mount	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/640	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports LP Elbow and 2 x Water Traps Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155/641	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports LP Luer Elbow and 2 x Water Traps Kit 4	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155A	Ventilator Breathing System Adult 2.4m Y-Piece Kit 10	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155AG	Argentic Parallel Circuit Adult 1.6m Y-Piece with 2 x Ports and 2 x Water Trap Kit 5	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-756	Adult Breathing System 22mm 1.6m Auto-Fill Chamber and Seal-Sealing Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-761	Adult Breathing System 22mm 1.6m Auto-Fill Chamber and 2 x Self-Sealing Water Traps	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-140 INA	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports Kit 6	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-140U	Ventilator Breathing System Adult 1.6m with Twin Monitoring Ports	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-150U	Ventilator Breathing System Adult 1.6m Y-Piece with 2 x Ports and 1 x Water Trap Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-233/4	Adult Smoothbore Limb 1.8m with 22mm/5mm Connector Plus HemaShield Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-460	Ventilator Breathing System Adult 1.6m with Flow Sensor	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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Ventilator Breathing Systems Adult Standard Non-Heated (Sterile)

TF: 056b

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
038-01-130STR	Ventilator Breathing System Adult 1.6m Kit 4	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-130G41STR	Ventilator Breathing System Adult 1.6m Kit with Luer Elbow	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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Ventilator Breathing Systems CPAP Non-Heated (Non-Sterile)

TF: 056b

Intended use: A sterile & 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	GMON CODE	GMON TERM	ROHS APPLIES Y/N
038-04-300	Adult CPAP Flexi-Lock Breathing System 1.6-4.0m 22mm + Ventilated Bifurcated Y-Piece with Collection Bag	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-940	Adult CPAP Breathing System 1.6m 22mm with Mask Filter & Synchroni-PEEP Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-940/1	Adult CPAP Breathing System 1.6m 22mm with Mask Size 5 and PEEP Valve 10cmH2O	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-940/2	Adult CPAP Breathing System 1.6m 22mm with T-Piece and Mask Size 5 and PEEP Valve 10cmH2O	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-940/3/1	Adult CPAP Breathing System 1.6m with Medium CPAP Mask B/V Filter & Synchroni-PEEP Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-941	Adult CPAP Breathing System 1.6m with Mask Filter and Synchroni-PEEP Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-946	Adult CPAP Single Limb Breathing System 1.6m with Bacterial/Viral Filter and Y-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950	Adult CPAP Single Limb Breathing System 2.0m with T-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/8	Adult CPAP Breathing System 2.0m 22mm with Water Trap + 2 x Temperature ports and 3.0m Limb Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/7	Adult CPAP Breathing System 2.1m 22mm with Washington T-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/9	Adult CPAP Breathing System 2.4m 22mm with T-Piece and Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/V	Adult CPAP Breathing System 2.0m 22mm with Safety Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/V4	Adult CPAP Breathing System 2.0m 22mm with T-Piece and Water Trap and Safety Valve and 0.8m Limb	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950/V8	Adult CPAP Breathing System 2.0m 22mm with Safety Valve and Nebuliser and 2.1m Oxygen Tubing	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-951	Adult CPAP Smoothbore Single Limb Breathing System 2.0m with T-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Bi-PAP Ventilator Breathing Systems (Non-Sterile)

TF: 056b

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	GMON CODE	GMON TERM	ROHS APPLIES Y/N
038-35-290	Adult Smoothbore Bi-PAP Breathing System 1.6m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-291	Adult Corrugated Bi-PAP Breathing System 1.6m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m with Exhalation Port	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292A	Adult Smoothbore Single Limb 1.6m with Leak Valve and 2.2m Monitoring Line for BiPAP Vision	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292B	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m Kit B	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292C	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m Kit C	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-293	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m Kit D	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292F	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m Kit F	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-294	Adult Smoothbore Bi-PAP Breathing System 1.6m with Exhalation Valve and Pressure Line	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-294/2	Pediatric Breathing System 1.6m 15mm with Ported Y-Piece + Exhalation Valve + 1.6m Bubble Tubing	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-295	Adult Bi-PAP Single Limb Breathing System 1.6m with Exhalation Port	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-299	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.6m with Exhalation Valve and B/V Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Breathing Systems - Single Limb with Exhalation Valve Ventilator (Sterile and Non-Sterile)

TF: 056b

Intended use: A sterile & 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	GMON CODE	GMON TERM	ROHS APPLIES Y/N
Non-Sterile					
038-01-120A	Bifurcated Smoothbore Circuit 1.6m 22mm with Ported Y-Piece Kit	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-288/1	Smoothbore Single Limb 1.6m with Exhalation Valve and Washington T-Piece Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-288/2	Smoothbore Single Limb Breathing System 1.6m 22mm with Exhalation Valve for Helia 1/Helia 5 / PASO1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-289	Oasis Circuit 1.6m with Flow Sensor & Exhalation Valve - KGO20400	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-357	Smoothbore Single Limb 1.6m 10mm with Exhalation Valve + Colder Connector/Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-321	Adult Bifurcated Smoothbore Circuit 1.6m 22mm for VS Ultra + Helia V1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-165/84/2	Pediatric Circuit 1.6m + Ported Y-Piece + Ported Swivel Elbow + 2.1m Tubing 3mm + 22F/22F Connector	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292A/1	Adult Smoothbore Single Limb 1.6m+Leak Valve + San-Vent 3/Flexible 22F Connectors for BiPAP Vision	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292G	Adult Smoothbore Single Limb 1.6m+Leak Valve+Water Trap+2.2m Monitoring Line with Filter+0.8m Limb	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-294/1	Pediatric Parallel Breathing System 1.6m with Exhalation Valve and 20cm Swivel Elbow Catheter Mount	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298	Adult Smoothbore Circuit 1.6m 22mm + Exhalation Valve + 20cm Smoothbore Catheter Mount	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-296/1	Adult Smoothbore Parallel Circuit 1.6m + Exhalation Valve + Colder Connector/Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-296/1	Adult Smoothbore Parallel Circuit 1.6m + Exhalation Valve + Colder Connector/Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Flexible 22F Connectors Kit	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/1	Adult Smoothbore Single Limb 1.6m + Exhalation Valve + Colder Connector + Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/2	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Colder Connector Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/3	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Flexible 22F Connectors Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/4	Adult Smoothbore Single Limb 1.6m with Exhalation Valve + Colder Connector + Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/5	Adult Smoothbore Single Limb 1.6m with Exhalation Valve + Colder Connector + Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/1	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Flexible 22F Connectors for VIVO 50	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/2	Adult Smoothbore Single Limb 1.6m with Exhalation Valve+Colder Connector/Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/3	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/4	Adult Smoothbore Single Limb 1.6m + Exhalation Valve + Colder Connector + Flexible 22F Connectors Kit 4	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/5	Adult Smoothbore Single Limb 1.6m 22mm with Exhalation Valve and Flexible 22F Connectors	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-298/6	Adult Smoothbore Single Limb 1.6m with Exhalation Valve and Flexible 22F Connectors Kit 5	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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038-61-321/6-645	Smoothbore Catheter Mount 40cm Swivel Elbow with Double Port Cap and Seal 15F/22M and 15M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-322	Smoothbore Catheter Mount 15mm Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-322U	Smoothbore Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-323	Smoothbore Catheter Mount 15mm Luer Lock Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-323U	Smoothbore Catheter Mount 15mm Luer Lock Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-324	Smoothbore Catheter Mount 15mm Elbow Elastomeric Cap with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-324X	Smoothbore Catheter Mount 15mm 10 cm Elbow Elastomeric Cap with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-325	Smoothbore Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-325U	Smoothbore Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-328	Smoothbore Catheter Mount 15mm Swivel Elbow with Double Port Cap and Seal 22F and 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-328A	Smoothbore Catheter Mount 15mm 160mm Swivel Elbow with Cap 22F and 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-328U	Smoothbore Catheter Mount 15mm Swivel Elbow with Double Port Cap+Seal 22F + 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-328U	Smoothbore Catheter Mount 15mm Swivel Elbow with Double Port Cap+Seal 22F + 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-326U	Smoothbore Catheter Mount 15mm Swivel Elbow with Double Port Cap and Seal 22F and 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
Flexi-Lock Tubing					
038-61-310	Flexi-Lock Catheter Mount 15mm with 15mm M and 15mm F Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310A	Flexi-Lock Catheter Mount 15mm with 15mm M and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310U	Flexi-Lock Catheter Mount 15mm with 15mm M and 15mm F Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/645-1	Flexi-Lock Catheter Mount 15mm Detach Swivel Elbow with Cap and Seal 22M/15F and 15M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-311	Flexi-Lock Catheter Mount 15mm with 22mm F and 15mm F Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-311U	Flexi-Lock Catheter Mount 15mm with 22mm F and 15mm F Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-312	Flexi-Lock Catheter Mount 15mm Low Profile Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-312A	Flexi-Lock Catheter Mount 15mm Low Profile Elbow with 22mm M and 15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-312U	Flexi-Lock Catheter Mount 15mm Low Profile Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-313	Flexi-Lock Catheter Mount 15mm Luer Lock Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-313A	Flexi-Lock Catheter Mount 15mm Luer Lock Elbow with 22mm M / 15 mm F and 15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-313U	Flexi-Lock Catheter Mount 15mm Luer Lock Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-314	Flexi-Lock Catheter Mount 15mm Elbow with Elastomeric Cap with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-315	Flexi-Lock Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-315U	Flexi-Lock Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm F/22mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N

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038-61-316	Flexi-Lock Catheter Mount 15mm Swivel Elbow with Double Port Cap and Seal 22F and 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-316K	Flexi-Lock Catheter Mount 15mm Swivel Elbow with 22mm F and 15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-316U	Flexi-Lock Catheter Mount 15mm Swivel Elbow with Double Port Cap and Seal 22F and 15F/22M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-316U-1	Flexi-Lock Catheter Mount 15mm Swivel Elbow with Double Port Cap and Seal 15F/22M and 15M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-317	Flexi-Lock Catheter Mount 15mm with 15mm F/22mm M and 22mm F Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-317/640	Flexi-Lock Catheter Mount 15mm with 15mm F/22mm M and 22mm F Connectors + Low Profile Elbow	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-319	Flexi-Lock Catheter Mount Short 15mm with 15mm M and 15mm F/22mm M Swivel Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-320	Flexi-Lock Catheter Mount Short 13mm with 15mm M and 15mm F Swivel Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/640	Flexi-Lock Catheter Mount 15mm Detachable Elbow with 22mm M and 15mm F/15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/641	Flexi-Lock Catheter Mount 15mm Detachable Luer Elbow with 22mm M and 15mm F/15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/643	Flexi-Lock Catheter Mount 15mm Detachable Swivel Elbow with 22mm F and 15mm F/15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/643U	Flexi-Lock Catheter Mount 15mm Detachable Swivel Elbow with 22mm F and 15mm F/15mm M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N
038-61-310/645	Flexi-Lock Catheter Mount 15mm Detach Swivel Elbow with Cap and Seal 22M/15F and 15M Connectors	Class Ila (Rule 2)	42478	Catheter Mount, Single Use	N



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Spirometry Kits (Non-Sterile)
TF: 056c

Intended use: Flexicare's Spirometry Kits are designed to be connected to a breathing circuit, a patient connection device and a spirometer / gas analyser device and are intended to provide a sample of the gas at the patient side, & allow for measuring of the gas concentration, pressure and flow. The device is positioned close to the patient and positioned between the breathing circuit and the tracheal tube, laryngeal mask or face mask.

Flexicare's Spirometry Kits are intended for use in hospital settings, such as operating theatres, or where general anaesthesia by inhalation is administered using low flow techniques, in ventilated patients. The devices are supplied non-sterile for single use only.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDC CODE	GMDC TERM	ROHS APPLIES Y/N
010-772	Adult Patient Spirometry Kit 2M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-773	Adult Patient Spirometry Kit 3M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-774	Adult Patient Spirometry Kit 4M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-775	Adult Patient Spirometry Kit 5M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-776	Adult Patient Spirometry Kit 6M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-782	Paediatric Patient Spirometry Kit 2M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-783	Paediatric Patient Spirometry Kit 3M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-784	Paediatric Patient Spirometry Kit 4M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-785	Paediatric Patient Spirometry Kit 5M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N
010-786	Paediatric Patient Spirometry Kit 6M	Class Ila (Rule 2)	61834	Breathing Circuit gas sampling/Monitoring set	N

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Anaesthesia Components (Sterile and Non-Sterile)
TF: 056c

Intended use: A non-sterile device intended to connect a breathing circuit breathing tube to an endotracheal (ET) tube, anaesthesia face mask, or other non-sampling breathing circuit component. It is constructed with standardized connecting dimensions and may be designed to connect breathing tubes from paediatric to adult sizes. It is typically made of plastic material and can have a straight or elbow-shaped design (excluding Y-piece connectors). Some designs may allow for partial rotation at the point of connection (a swivel) and may include a suction port or gas sampling port. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDC CODE	GMDC TERM	ROHS APPLIES Y/N
Connectors/Adapters					
010-601	Straight Connector 22mm M / F with Right Angle Barb Outlet 6mm	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-602	Straight Connector 22mm M / F with Right Angle Luer Lock Port with Retainer Cap	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-603	Straight Connector 22mm F / F with Right Angle Luer Lock Port with Retainer Cap	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-604	Straight Connector 22mm F / F with Port and Retainer Plug	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-605	Straight Connector 22mm M / F with Port and Retainer Plug	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-606	Straight Connector 22mm M / M with Port and Retainer Plug	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-607	Reservoir Bag Angled Connector For GE Carestation	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-608	Bi-PAP Connector 22mm-15F/22mm with Exhaust Valve and Pressure Line	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-608U	Bi-PAP Connector 22mm-15F/22mm with Exhaust Valve and Pressure Line	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-609	Serrated Connector 22mm M / 15mm M	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-610	Serrated Connector 22mm M / F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-611	Straight Connector 22mm M / M - 15mm F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-611U	Straight Connector 22mm M / M - 15mm F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-612	Straight Connector 22mm F - 15mm M	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-612U	Straight Connector 22mm F - 15mm M	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-613	Straight Connector 15mm M / M	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-613U	Straight Connector 15mm M / M	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-614	Straight Connector 15mm M / F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-614U	Straight Connector 15mm M / F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-617	Straight Connector 22mm M - 30mm F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-618	Straight Connector 22F / 22F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-618U	Straight Connector 22F / 22F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-619	Straight Connector 22M/22F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-626	Straight Connector 22mm Male / 30mm Male	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-627	Straight Flexible Connector 15M / 22F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-659	Straight Connector 22F/15F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-671	Serrated Connector 22F / 15F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-672	Straight Connector 15M/22M-15F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N
010-673	Straight Connector 22F-22M/15F	Class Ila (Rule 2)	61346	Tube/mask breathing circuit connector, single-use, non-sterile	N

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038-01-2422	Flexi-Lock Tubing Limb 0.7m To 2.0m 22mm Tube with 2 x 22mm F Sarrazed and 22M/22M/15F Connectors	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-61-830N/LJ	Reservoir Bag 3 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-01-2423	Flexi-Lock Tubing Limb 0.4m to 0.8m 22mm Tube with 21 Res Bag and 22mm F Sarrazed Connector	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-61-830N/LJ	Reservoir Bag 3 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-01-2424	Flexi-Lock Limb 22mm 0.7-2.3m with 22mm F Connector and 2L Reservoir Bag	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-62-810N/LJ	Reservoir Bag 1 Litre with 22mm Female Connector - Closed Tail	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-01-2425	Flexi-Lock Limb 22mm 0.4-1.2m with 22mm F Connector and 2L Reservoir Bag	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-62-810N/LJ	Reservoir Bag 1 Litre with 22mm Female Connector - Closed Tail	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-01-247	Flexi-Lock Limb 22mm 1.7m to 3m 22mm Tube without Connectors	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-62-810N/LX	Reservoir Bag 0.5 Litre with 22mm Female Connector - Closed Tail	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-02-248	Flexi-Lock Tubing Limb 1.5m 15mm Tube with 2 x 22mm Female Connectors	Class Ila (Rule 2)	63534	Inspiratory/Respiratory limb respiratory tubing, single-use, non-sterile	N	038-63-805N/LJ	Reservoir Bag 0.5 Litre with 22mm Female Connector - Closed Tail	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-700	Monitoring Line 2m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-63-805N/LJ	Reservoir Bag 0.5 Litre with 22mm Female Connector - Open Tail	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-700U	Monitoring Line 2m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-700A	Monitoring Line 2m with 1 x Male Luer Connector and 1 x Silicone Sleeve	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-700X	Monitoring Line 3m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-701	Monitoring Line 3m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-701U	Monitoring Line 3m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-702	Monitoring Line 1.0M with Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-704	Monitoring Line 4m with Male / Male Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-705	Monitoring Line 2m with Female / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-705U	Monitoring Line 2m with Female / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-709	Monitoring Line 2m with Female / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-710	Monitoring Line 2m with Male / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-710U	Monitoring Line 2m with Male / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-710X	Monitoring Line 2m with Male / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-712	Monitoring Line 3m, Filter, Male to Microstream Type Luer	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-712U	Monitoring Line 10L, Filter, Male to Microstream Type Luer	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-720	LuerSafe Monitoring Line 2m with Male Luer / Male Luer Safe Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-721	LuerSafe Monitoring Line 3m with Male Luer / Male Luer Safe Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-725	LuerSafe Monitoring Line 2m with Male Luer Safe / Female Luer Connectors	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-683	Male-Male Luer Adapter	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-683U	Male-Male Luer Adapter	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-789K	Pressure Line 1.8m - 5.2mm OD x 3.4mm ID with Male Luer Lock Connector	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
010-781	Neonatal Pressure Line 1.8m & right angled connector	Class Ila (Rule 2)	45566	Gas-sampling/monitoring respiratory tubing, single-use	N	038-62-810N/LJ	Reservoir Bag 1 Litre Closed Tail with 22M/22M Straight Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-61-830N/LJ	Reservoir Bag 2L Lateral with 22mm F Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N	038-61-830N/LJ	Reservoir Bag 2L Lateral with 22mm F Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N	038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N	038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N	038-61-830N/LJ	Reservoir Bag 2 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N
038-61-830N/LJ	Reservoir Bag 3 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N	038-61-830N/LJ	Reservoir Bag 3 Litre with 22mm Female Connector	Class Ila (Rule 2)	34877	Breathing circuit bag, single-use	N

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010-685	Flexible Connector	Class Ila (Rule 2)	61347	Tubemask breathing circuit connector, single-use, sterile	N	PEEP Valves (Non-Sterile) TF: 056c					
010-685U	Flexible Connector	Class Ila (Rule 2)	61347	Tubemask breathing circuit connector, single-use, sterile	N						
010-686	T-Piece with 8M/8F Luer Right angled connector Extended	Class Ila (Rule 2)	61346	Tubemask breathing circuit connector, single-use, non-sterile	N						
038-01-2335TR	Adult Smoothbore Limb 1.5m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 1.5m 22mm with Flexible 22mm F Connectors and 3L Res Bag	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 0.3m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 0.4m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 0.6m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 0.8m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 1.0m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 1.2m with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 2.1m with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-01-2335TR	Adult Smoothbore Limb 1.8m 22mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						
038-03-2348TR	Neonatal Smoothbore Limb 1.5m 10mm with Flexible 22mm F Connectors	Class Ila (Rule 2)	63962	Inspiratory/Respiratory limb respiratory tubing, single-use, sterile	N						

Intended use: A non-sterile device used in a respiratory or anaesthesia breathing circuit or system to maintain a selected level of positive end expiratory pressure (PEEP) in a patient's airway during ventilation. The device is typically constructed of plastic and metal materials and has a valve(s) actuated with a spring(s) to provide the airway resistance, and an adjustable knob or dial (usually graduated) to adjust the resistance level typically between 5 to 20 cmH₂O. It is used with ventilators, stand-alone breathing systems for oxygen delivery, pulmonary resuscitators, or anaesthetic breathing systems often having an expiratory valve function. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-35-902	PEEP Valve 2.5cmH ₂ O (Black)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-905	PEEP Valve 5.0cmH ₂ O (Blue)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-907	PEEP Valve 7.5cmH ₂ O (Yellow)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-910	PEEP Valve 10.0cmH ₂ O (Green)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-912	PEEP Valve 12.5cmH ₂ O (Pink)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-915	PEEP Valve 15cmH ₂ O (Red)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N
038-35-920	PEEP Valve 20cmH ₂ O (Brown)	Class Ila (Rule 2)	46823	PEEP Valve, Single-use	N



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Capnography Connector (Non-Sterile)

TF: 056c

Intended use: CapnoCare is a capnography connector used in conjunction with breathing circuits and samples EtCO₂ during critical and surgical situations. The device is connected in line with laryngeal mask airways, ET tubes or anaesthesia facemasks. CapnoCare is used for adult, paediatric and infant / neonatal patients. The device is intended for both ventilated and spontaneously breathing patients within hospital operating theatres, anaesthetic rooms and recovery (PACU), during emergency and standard anaesthesia practice.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANHIX IX	GMGN CODE	GMGN TERM	RHNS APPLIES Y/N
010-740	Hydrophobic Disc Filter Luer Lock Female to Male	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-740U	Hydrophobic Disc Filter Luer Lock Female to Male	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-741	Hydrophobic Disc Filter Luer Slip Female to Luer Slip	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-741U	Hydrophobic Disc Filter Luer Slip Female to Luer Slip	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-742	Hydrophobic Disc Filter Luer Lock Male to Female	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-742U	Hydrophobic Disc Filter Luer Lock Male to Female	Class Ila (Rule 2)	61134	Heatmoisture exchange/microbial filter, sterile	N
010-750	CapnoCare Capnography Connector 3m Filter with Male Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-750U	CapnoCare Capnography Connector 3m Filter with Male Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-755	CapnoCare Capnography Connector 3m Filter with Female Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-755U	CapnoCare Capnography Connector 3m Filter with Female Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-760	CapnoCare Capnography Connector 3m Filter with Luer Slip	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-760U	CapnoCare Capnography Connector 3m Filter with Luer Slip	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-762	CapnoCare Capnography Connector 3m Filter, Microstream Type Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N
010-762U	CapnoCare Capnography Connector 3m Filter, Microstream Type Luer	Class Ila (Rule 2)	43566	Gas-sampling/monitoring respiratory tubing, single-use	N

Bubble CPAP Systems (Sterile)

TF: 060

Intended use: Flexicare Bubble CPAP System is intended to provide Continuous Positive Airway Pressure (CPAP) to spontaneously breathing neonates and infants requiring respiratory support. Used alongside a Respiratory Gas Humidifier, Flexicare Bubble CPAP System delivers warmed and humidified inspiratory gases to the patient via a nasal interface. The Bubble CPAP System is intended to be used by trained personnel in the hospital clinical environment such as the non-tertiary special care nurseries (SCNs) and neonatal intensive care unit (NICU). The devices are supplied sterile and for single use only.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANHX U	GMON CODE	GMON TERM	RHS APPLIES Y/N
036-10-300	Bubble CPAP Generator	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-lane	N
036-33-190	Bubble CPAP System (Kit 1)	Class Ila (Rule 2 & 5)	35202	CPAP nasal oxygen cannula	N
036-33-180/2	Bubble CPAP System (Kit 2) Infant Nasal CPAP Cannula Set Size 00	Class Ila (Rule 2 & 5)	35202	CPAP nasal oxygen cannula	N
036-33-190/3	Bubble CPAP System (Kit 3) Infant Nasal CPAP Cannula Set Size 0	Class Ila (Rule 2 & 5)	35202	CPAP nasal oxygen cannula	N
036-33-180/4	Bubble CPAP System (Kit 4) Infant Nasal CPAP Cannula Set Size 1	Class Ila (Rule 2 & 5)	35202	CPAP nasal oxygen cannula	N

Adult Heated Wire Breathing Systems (Sterile)

TF: 060

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	GMGN CODE	GMGN TERM	RHS APPLIES Y/N
038-31-252U	Adult Ventymyst Dual Heated Wire Breathing System 1.6m K1	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-252K	Ventymyst Adult Dual Heated Wire Breathing System Line - K1	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-252JU	Adult Ventymyst Dual Heated Wire B/S 1.5m K3/1 K4	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-253	Adult Ventymyst Dual Heated Wire Breathing System 1.6m K2	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-253K	Ventymyst Adult Dual Heated Wire Breathing Pressure Line - K2	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-253J1	Adult Ventymyst Dual Heated Wire Breathing System 1.6m K1	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-253U	Adult Ventymyst Dual Heated Wire B/S 1.5m K3/1	Class I(a) (Rule 2)	37706	Ventilator breathing circuit, single-use	N



Humidification Circuits - Adult & Paediatric Heated Wire Breathing Systems (Single use, Sterile)

TF: 060

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	OMDN CODE	GMIND TERM	RHQS APPLIES Y/N
Adult Heated Wire Breathing Systems					
038-01-1633TR	Ventilator Single Heated Wire Breathing System Adult 1.6m with Water Trap Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-748K	Dual Heated Wire B/S 1.6m + Aseptic Fil Chamber + Cath Mount and MDI Seal	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-748KS	Adult Dual HW B/S System 1.6m Y-Place Cath Mount with L-Elbow Aseptic Chamber 0.5m Limb (Sterile)	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-101	Adult Single Heated Wire Breathing System 22mm 1.6m Water Trap and Aseptic Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-101U	Adult Single Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-102	Adult CPAP Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-102U	Adult CPAP Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-844U	Adult CPAP Heated Wire Breathing System 1.6m with Mask Adult B Chamber and 2.5m Snap Valve	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-201	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-201J	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-201U	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-202	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-202U	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-203	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-203K	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-203U	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 3	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-301	Adult Dual Heated Wire Convertible Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-301U	Adult Dual Heated Wire Convertible Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-301X	Adult Dual Heated Wire Convertible Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-401	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-401U	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-402	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-402U	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-402J	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-403	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-403U	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 3	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N
038-01-404	Adult Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-404U	Adult Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37708	Ventilator breathing circuit, single-use	N

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038-31-40S	Adult Single Limb Heat Wire Breathing System 1.6m with Veoflo Small Kit S	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-40U	Adult Single Limb Heated Wire Breathing System 1.6m with Veoflo Small Kit S	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-41Z	Adult Single Limb Heated Wire (1.6m) with Bacterial Vial Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-50I	Adult CPAP / HFOT Staircase Single Limb Heated Wire Breathing System 22mm 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-50IU	Adult CPAP / HFOT Staircase Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60I	Adult Bi-PAP Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60IU	Adult Bi-PAP Single Limb Heated Wire B/S 1.6m (1.6m) Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60T	Adult Bi-PAP Single Limb Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60TU	Adult Bi-PAP Single Limb Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60Z	Adult BiPAP Single Limb HW B/S 1.6m X 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-60ZU	Adult BiPAP Single Limb HW B/S 1.6m X 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-65VNA	Adult Embossed BPAP Single Limb Heated Wire B/S 1.6m X 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-74E	Dual Heated Wire Breathing System 1.6m with Ported Y-Piece and Manual Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-74F	Dual Heated Wire Breathing System 1.6m with Ported Y-Piece and Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-74H	Dual Heated Wire Breathing System 1.6m with Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-74HU	Dual Heated Wire B/S 1.6m + Auto Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-74U	Adult Single Heated Wire Breathing System 22mm 1.6m Water Trap and Auto Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-76U	Adult Circuit/HW Insp HPSM Water Trap & Aqualit Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-76UA	Adult Single Heated Wire Breathing System 22mm 1.6m Water Trap and Auto Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-77ESR	Adult Breathing System 22mm 1.6m with Y Piece and MDI AFIL Chamber - W/Trap DSFlow Carb Mount	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-77EST	Adult HW B/S 1.6m-Water Trap 1.2m-Limb-In-Mask Res Sealite	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95A	Adult CPAP Heated Wire Breathing System 2.4m Chamber 2x1-Piece B/V Filter and Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95B	Adult CPAP Heated Wire Breathing System 1.6m Mask Auto-Fill Chamber 1cmHQ & 20cmHQ PEEP Valves	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95C	Adult CPAP Heated Wire Breathing System 1.6m with Mask Auto-Fill Chamber and 5cm Peep Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95D	ARGENTIC PAP HW B/S 1.6M-EMFOAL TRACH-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95E	ARGENTIC PAP HW B/S 1.6M-ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95F	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95G	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95H	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95I	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95J	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95K	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95L	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95M	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95N	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95O	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95P	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95Q	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95R	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95S	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95T	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95U	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95V	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95W	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95X	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95Y	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-95Z	ARGENTIC PAP HW B/S 1.6M-PAEDS ADULT VEOLFO-B/V FILTER	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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Humidification Circuits - Adult & Paediatric Heated Wire Breathing Systems (Single use, Non-Sterile)

TF: 060

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	GMON CODE	GMON TERM	ROHS APPLIES Y/N
Adult Heated Wire Breathing Systems					
038-01-162	Heated Wire 1.6m Limb With 22mm Adaptor M/F	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-163	Ventilator Single Heated Wire Breathing System Adult 1.6m with Water Trap Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-163A	Smoothbore Ventilator Single Heated Wire Breathing System Adult 1.6m with Water Trap Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-163	Ventilator Single Heated Wire Breathing System Adult 1.6m with Water Trap Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-164	Ventilator Adult Heated Wire Breathing System Adult 1.6m Y-Piece with 2 x Ports Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-101NS	Adult Single Heated Wire Breathing System 22mm 1.6m Water Trap & Auto-Fill Chamber (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-102NS	Adult CPAP Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-203NS	Adult Dual Heated Wire Breathing System 22mm 1.6m Kit 3 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-203NS	Adult Ventimyst Dual Heated Wire Breathing System 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-203NS	Adult Ventimyst Dual Heated Wire Breathing System 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-303NS	Adult Dual Heated Wire Convertible Breathing System 22mm 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-303NS	Adult Dual Heated Wire Convertible Breathing System 22mm 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-403NS	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-403NS	Adult CPAP / HFOT Single Limb Heated Wire Breathing System 22mm 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-403NS	Adult Single Limb Heated Wire Breathing System 1.6m Kit 4 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-403NS	Adult Single Limb Heated Wire Breathing System 1.6m with Vento Small Kit 5 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-403NS	Adult Bi-PAP Single Limb Heated Wire Breathing System 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
Paediatric Heated Wire Breathing Systems					
038-02-160	Paediatric Single Heated Wire Parallel Circuit 1.6m with Ported Y-Piece + 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-160A	Paediatric Smoothbore Single Heated Wire Breathing System 1.6m with Ported Y-Piece + 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-160AG	Paediatric Single Heated Wire Vent Breathing System 1.6m with Ported Y-Piece + 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-161	Paediatric Single Heated Wire Parallel Circuit 1.6m with Pressure Port + 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-161A	Paediatric Smoothbore Single Heated Wire Vent Breathing System 1.6m with Ported Y-Piece + 1 Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

EC Declaration of Conformity



EC Declaration of Conformity



Humidification Circuits - Neonatal Heated Wire Breathing Systems (Single Use, Sterile)

TF: 060

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	GMON CODE	GMON TERM	ROHS APPLIES Y/N
038-33-101	Neonatal Single Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-101/2	Neonatal Single Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-102	Neonatal Single Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103	Neonatal Smoothbore Single Heated Wire System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103/5	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103/5	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103/5	Neonatal Single Heated Wire Breathing System 1.6m B-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103/5	Neonatal Single Heated Wire Breathing System 1.6m B-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201	Neonatal Dual Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202	Neonatal Dual Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201/5	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202/5	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201/5	Neonatal Dual Heated Wire Breathing System 1.6m B-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202/5	Neonatal Dual Heated Wire Breathing System 1.6m B-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-300/1	Neonatal Shielded Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-300/1	Neonatal Circuit Single Limb Heated Wire (15mm Shielded Tube) & Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-340U	Neonatal Single Heated Wire Breathing System 1.25m with 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-340S/1	Neonatal Single Heated Wire Breathing System 1.6m with Water Trap including Extension Limb	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-341C	Neonatal 10mm Single Heated Wire 1.6m B-Type (B-LOG)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-342C	Neonatal Dual Heated Wire Breathing System 1.25m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-346U	Neonatal Dual Heated Wire Breathing System 1.25m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-356U	Neonatal Dual Heated Wire Breathing System with Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-311C	Neonatal Universal H/Wire B/System-Clover + Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-340C	Neonatal Single Heated Wire 1.6m Breathing System Water Trap Auto-Fill Chamber Incubator Extension	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-340C/1	Neonatal Single Heated Wire Breathing System 1.25m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-340K	Neonatal Single Heated Wire Breathing System 1.6m with Water Trap and Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-346C	Neonatal Dual Heated Wire Breathing System 1.25m with Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-101U	Neonatal Single Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

038-33-102U	Neonatal Single Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201U	Neonatal Dual Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202U	Neonatal Dual Heated Wire Breathing System 1.6m Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-203	Neonatal Dual Heated Wire Breathing System 1.6m Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-203U	Neonatal Dual Heated Wire Breathing System 1.6m Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-301U	Neonatal Shielded Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-402	Neonatal Single Limb Heated Wire Breathing System HFOT 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-402U	Neonatal Single Limb Heated Wire Breathing System HFOT 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252	Neonatal Ventimyst Neonatal Dual Heated Wire with Chamber - Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252U	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252U	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252S	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) S-Type (Kit 1)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252/8K	Ventilator with Chamber - Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252/8S	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) Kit 6	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252FG	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252/8FC	Ventimyst Dual Heated Wire B/S 1.6m (B*) S-Type (Kit 1)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-253	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-253S	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (B*) S-Type (Kit 2)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-38-960A	Neonatal Embedded Single Limb Heated Wire Circuit	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340/1	Neonatal Single Heated Wire Breathing System 1.25m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Humidification Circuits - Neonatal Heated Wire Breathing Systems (Single Use, Non-Sterile) TF: 060

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
038-03-341	Neonatal Single Heated Wire Breathing System 1.25m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-342	Neonatal Heated Wire B/S 1250mm (Dräger Babylog)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-342AG	Argonite Neonatal Heated Wire Breathing System 1.25m (Dräger Babylog)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340	Neonatal Single Heated Wire Breathing System 1.6m with 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340AG	Argonite Neonatal Single Heated Wire Breathing System 1.25m with 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340 IHA	Neonatal Single Heated Wire Breathing System 1.6m with 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-348	Neonatal Dual Heated Wire Breathing System 1.25m Clover	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-348AG	Argonite Neonatal Dual H/Wire B/S System 1.6m Clover	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-348K	Neonatal H/Wire B/S System 1200mm Clover + Auto Chamber Pressure Line and Accessories	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-101SNS	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-101NS	Neonatal Single Heated Wire Breathing System 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-102SNS	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-102NS	Neonatal Single Heated Wire Breathing System 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201SNS	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201NS	Neonatal Dual Heated Wire Breathing System 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202SNS	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202NS	Neonatal Dual Heated Wire Breathing System 1.6m Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252SNS	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (837) S-Type (Kit 1) (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-252NS	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (837) Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-253SNS	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (837) S-Type (Kit 2) (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-253NS	Neonatal Ventimyst Dual Heated Wire B/S 1.6m (837) Kit 2 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-402NS	Neonatal Single Limb Heated Wire Breathing System HFOT 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Humidification Chambers (Sterile) TF: 060

Intended use: Sterile/single use device designed to heat and humidify air/oxygen inspired by a patient to help maintain the mucous membranes of the respiratory tract typically during periods of prolonged respiratory support/therapy (e.g., mechanical ventilation, BPAP/CPAP therapy). The heated/humidified gases are delivered to the patient's airway and lungs via the nose/mouth or a tracheostoma in association with a parent respiratory device (e.g., ventilator, BPAP/CPAP unit).

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-31-742	Double Valve Auto-Fill Humidification Chamber Sterile	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-742U	Double Valve Auto-Fill Humidification Chamber	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-743	Double Valve Auto-Fill Humidification Chamber for BPAP	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-740	Auto-Fill Humidifier Chamber Sterile	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-740 IHA	Auto-Fill Humidifier Chamber Sterile	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-750	Humidifier Chamber - Manual Fill Sterile	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-750U	Humidifier Chamber - Manual Fill	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N
038-31-750A	Humidifier Chamber - Manual Fill without Taping	Class Ila (Rule 2)	60699	Inspiratory line humidification chamber, single-use	N



LarySeal Multiple (Sterile) TF: 082b

Intended use: A sterile curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be radiopaque, and have a distal inflatable cuff to seal against the tracheal wall and have a built-in pilot balloon for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-94-110	LarySeal Multiple Laryngeal Mask Airway Silicone Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-110U	LarySeal Multiple Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-115	LarySeal Multiple Laryngeal Mask Airway Silicone Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-115U	LarySeal Multiple Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-120	LarySeal Multiple Laryngeal Mask Airway Silicone Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-120U	LarySeal Multiple Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-125	LarySeal Multiple Laryngeal Mask Airway Silicone Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-125U	LarySeal Multiple Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-130	LarySeal Multiple Laryngeal Mask Airway Silicone Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-130U	LarySeal Multiple Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-140	LarySeal Multiple Laryngeal Mask Airway Silicone Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-140U	LarySeal Multiple Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-150	LarySeal Multiple Laryngeal Mask Airway Silicone Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N
038-94-150U	LarySeal Multiple Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, reusable	N

LarySeal Blue (Sterile) TF: 082c

Intended use: A sterile curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be radiopaque, and have a distal inflatable cuff to seal against the tracheal wall and have a built-in pilot balloon for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-94-210	LarySeal Blue Laryngeal Mask Airway Silicone Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-210U	LarySeal Blue Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-215	LarySeal Blue Laryngeal Mask Airway Silicone Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-215U	LarySeal Blue Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-220	LarySeal Blue Laryngeal Mask Airway Silicone Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-220U	LarySeal Blue Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-225	LarySeal Blue Laryngeal Mask Airway Silicone Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-225U	LarySeal Blue Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-230	LarySeal Blue Laryngeal Mask Airway Silicone Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-230U	LarySeal Blue Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-240	LarySeal Blue Laryngeal Mask Airway Silicone Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-240U	LarySeal Blue Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-250	LarySeal Blue Laryngeal Mask Airway Silicone Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-250U	LarySeal Blue Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-610	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-615	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-620	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-625	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-630	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-640	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-650	LarySeal Blue Laryngeal Mask Airway Silicone Pack Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N

LarySeal Clear (Sterile)

TF-082d

Intended use: A sterile curved tube is used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be redopacque, and have a distal inflatable cuff to seal against the oropharynx well as have a built-in pivot bottom for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMN CODE	GMN TERM	ROHS APPLIES Y/N
038-94-310	LarySeal Clear Laryngeal Mask Airway Size 1	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-310 INA	LarySeal Clear Laryngeal Mask Airway Size 1	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-310U	LarySeal Clear Laryngeal Mask Airway Size 1	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-310P	LarySeal Clear Laryngeal Mask Airway Size 1 with Lubricant and Inflator	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-315	LarySeal Clear Laryngeal Mask Airway Size 1.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-315 INA	LarySeal Clear Laryngeal Mask Airway Size 1.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-315U	LarySeal Clear Laryngeal Mask Airway Size 1.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-315P	LarySeal Clear Laryngeal Mask Airway Size 1.5 with Lubricant and Inflator	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-320	LarySeal Clear Laryngeal Mask Airway Size 2	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-320 INA	LarySeal Clear Laryngeal Mask Airway Size 2	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-320U	LarySeal Clear Laryngeal Mask Airway Size 2	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-320P	LarySeal Clear Laryngeal Mask Airway Size 2 with Lubricant and Inflator	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-325	LarySeal Clear Laryngeal Mask Airway Size 2.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-325 INA	LarySeal Clear Laryngeal Mask Airway Size 2.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-325U	LarySeal Clear Laryngeal Mask Airway Size 2.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-325P	LarySeal Clear Laryngeal Mask Airway Size 2.5 with Lubricant and Inflator	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-330	LarySeal Clear Laryngeal Mask Airway Size 3	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-330 INA	LarySeal Clear Laryngeal Mask Airway Size 3	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N

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038-94-330U	Laryseal Clear Laryngeal Mask Airway Size 3	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-330P	Laryseal Clear Laryngeal Mask Airway Size 3 with Lubricant and Inflator	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-340	LarySeal Clear Laryngeal Mask Airway Size 4	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-340 9NA	LarySeal Clear Laryngeal Mask Airway Size 4	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-340U	Laryseal Clear Laryngeal Mask Airway Size 4	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-340P	Laryseal Clear Laryngeal Mask Airway Size 4 with Lubricant and Inflator	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-350	LarySeal Clear Laryngeal Mask Airway Size 5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-350 9NA	LarySeal Clear Laryngeal Mask Airway Size 5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-350U	Laryseal Clear Laryngeal Mask Airway Size 5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-350P	Laryseal Clear Laryngeal Mask Airway Size 5 with Lubricant and Inflator	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-710	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 1	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-710U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 1	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-715	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 1.5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-715U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 1.5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-720	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 2	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-720U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 2	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-725	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 2.5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-725U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 2.5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-730	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 3	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-730U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 3	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-740	LarySeal Clear Laryngeal Mask Airway Size 4 Slimline Pack	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-740U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 4	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-750	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-750U	Laryseal Clear Laryngeal Mask Airway Slimline Pack Size 5	Class IIA (Rule 5)	45036	Laryngeal mask airway, single-use	N

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LarySeal MRI (Sterile)

TF: 0820

Intended use: A sterile curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be radiopaque, and have a distal inflatable cuff to seal against the tracheal wall and have a built-in pilot balloon for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMGN CODE	GMGN TERM	RHDS APPLIES Y/N
038-94-410	LarySeal MRI Laryngeal Mask Airway Size 1	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-410U	LarySeal MRI Laryngeal Mask Airway Size 1	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-415	LarySeal MRI Laryngeal Mask Airway Size 1.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-415U	LarySeal MRI Laryngeal Mask Airway Size 1.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-420	LarySeal MRI Laryngeal Mask Airway Size 2	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-420U	LarySeal MRI Laryngeal Mask Airway Size 2	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-425	LarySeal MRI Laryngeal Mask Airway Size 2.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-425U	LarySeal MRI Laryngeal Mask Airway Size 2.5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-430	LarySeal MRI Laryngeal Mask Airway Size 3	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-430U	LarySeal MRI Laryngeal Mask Airway Size 3	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-440	LarySeal MRI Laryngeal Mask Airway Size 4	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-440U	LarySeal MRI Laryngeal Mask Airway Size 4	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-450	LarySeal MRI Laryngeal Mask Airway Size 5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-450U	LarySeal MRI Laryngeal Mask Airway Size 5	Class I(a) (Rule 5)	45036	Laryngeal mask airway, single-use	N

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LarySeal Flexi (Sterile)

TF: 0828

Intended use: A sterile curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be radiopaque, and have a distal inflatable cuff to seal against the tracheal wall and have a built-in pilot balloon for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	GMN TERM	RHS APPLIES Y/N
038-94-510	Laryseal Flex Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-510U	Laryseal Flex Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-515	Laryseal Flex Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-515U	Laryseal Flex Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-520	Laryseal Flex Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-520U	Laryseal Flex Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-525	Laryseal Flex Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-525U	Laryseal Flex Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-530	Laryseal Flex Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-530U	Laryseal Flex Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-540	Laryseal Flex Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-540U	Laryseal Flex Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-550	Laryseal Flex Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N
038-94-550U	Laryseal Flex Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45038	Laryngeal mask airway, single-use	N



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LarySeal Pro (Sterile)
 TF: 082g

Intended use: A sterile curved tube used in inhalational anaesthesia and resuscitation to facilitate and secure airway patency for the delivery and exchange of gases in spontaneously breathing and ventilated patients. It is inserted into the pharyngeal cavity to prevent the tongue from obstructing the anatomical airway. It may include a 15 mm connector that attaches to a breathing circuit or manual resuscitator, be radiopaque, and have a distal inflatable cuff to seal against the tracheal wall and have a built-in pilot balloon for cuff pressure monitoring. It is available in various sizes/designs and is typically made of silicone/plastic materials. Available in both single-use and reusable variants.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-94-810	LarySeal Pro Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-810U	LarySeal Pro Laryngeal Mask Airway Size 1	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-815	LarySeal Pro Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-815U	LarySeal Pro Laryngeal Mask Airway Size 1.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-820	LarySeal Pro Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-820U	LarySeal Pro Laryngeal Mask Airway Size 2	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-825	LarySeal Pro Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-825U	LarySeal Pro Laryngeal Mask Airway Size 2.5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-830	LarySeal Pro Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-830U	LarySeal Pro Laryngeal Mask Airway Size 3	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-840	LarySeal Pro Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-840U	LarySeal Pro Laryngeal Mask Airway Size 4	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-850	LarySeal Pro Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N
038-94-850U	LarySeal Pro Laryngeal Mask Airway Size 5	Class Ila (Rule 5)	45036	Laryngeal mask airway, single-use	N


Bacterial/Viral Filter with HME (Sterile)
 TF: 083

Intended use: A non-sterile device intended to be placed within a breathing circuit proximal to the patient, to remove and retain microbes whilst capturing the patient's exhaled heat and moisture so that they can be used to heat and humidify the therapeutic gases inspired by the patient. It is typically a plastic housing which contains both a bidirectional microbial filter, intended to reduce the risk of cross-contamination between patients, and a heat/moisture exchanger (HME), intended to maintain the mucous membranes of the respiratory tract. It is typically used during anaesthesia or periods of prolonged respiratory support/therapy. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Bacterial/Viral Filter Sterile					
038-41-350STR	ThermoShield Adult Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-350STRJ	ThermoShield Adult Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-350J11STR	ThermoShield Adult Bacterial Viral HMEF with Flexi-Lock Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-350J11STR BRZ	ThermoShield Adult Bacterial Viral HMEF with Flexi-Lock Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-350STR	ThermoShield Adult Angled Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355STR J	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355STR J	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355FSTR	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355HSTR	ThermoShield Adult Bacterial Viral HMEF with Luer Port + 22F/15F Flexi-Lock Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355STR	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-355STRU	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-358STR	LuerSafe Adult Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-358STR	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-356STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port Sterile	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-356STRJ	ThermoShield Adult Bacterial Viral HMEF with Luer Port Sterile	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-357STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port and Low Profile Elbow Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-41-359STR	ThermoShield Adult Bacterial Viral HMEF with Luer Port Swivel Elbow W/ Cap Flexi-Lock Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N

038-42-350STR	ThermoShield Mini Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-350J11STR	ThermoShield Mini Bacterial Viral HMEF + Flexi-Lock Catheter Mount	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-100-000	Hygrovent Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
HF55	HF55 Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
HF55J	HF55 Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
HF55-LM88	Filtro HME Tarnato Adulto	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
352-219-010C	HME Booster T-Piece WFL Kit 3	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
354-200-030	HME-Booster T-piece with Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
354-200-000J	HME-Booster T-piece with Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
354-205-010	HME-Booster T-Piece Kit 2	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
354-205-010J	HME-Booster T-Piece Kit 2	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
354-215-010	HME-Booster T-Piece Kit 1	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-000-000	Hygrovent Gold Basic	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-001-010E	Hygrovent Gold Comfort	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-001-010E TR	Hygrovent Gold Comfort	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-005-010E	Hygrovent Gold Standard	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-021-010F	Hygrovent Gold Comfort WFL	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-031-010A	Hygrovent Gold Comfort Plus	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-031-010A TR	Hygrovent Gold Comfort Plus	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
355-105-015F	Hygrovent Gold Standard Flex	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
450-105-001	Hygrovent Bacterial Viral HMEF with Flexi-Lock Straight Catheter Mount 15F-22M/15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
450-105-001 BRZ	Hygrovent Bacterial Viral HMEF with Flexi-Lock Straight Catheter Mount 15F-22M/15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-355STR	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-355STRJ	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N

038-42-355A3TR	ThermoShield Mini Bacterial Viral HMEF Luer Port Flexi-Lock Catheter Mount 22M/15F + Elbow	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-355FSTR	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-355HSTR	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Flexi-Lock Catheter Mount 22M/15F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-356STR	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-42-356STRJ	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
038-43-355STR	ThermoShield Neonatal Bacterial Viral Filter and HME with Luer Port	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-200-000	Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-200-000J	Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-210-000	Hygrovent S Angled Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-210-000J	Hygrovent S Angled Bacterial Viral HMEF Small	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-510-000	Hygrovent Child Angled Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-510-000A	Hygrovent Child Angled HME Filter Sterile	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-510-000J	Hygrovent Child Angled Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-520-000	Hygrovent Child Straight Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-520-000A	Hygrovent Child Straight HME Filter Sterile	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
300-520-000J	Hygrovent Child Straight Bacterial Viral HMEF	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
420-201-015	Hygrovent S Bacterial Viral HMEF Small with Smoothbore Catheter Mount 15cm with Detachable Elbow 22F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
422-205-015	Hygrovent S Bacterial Viral HMEF Small with Flexi-Lock Straight Catheter Mount 15F - 22F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
422-205-015 BRZ	Hygrovent S Bacterial Viral HMEF Small with Flexi-Lock Straight Catheter Mount 15F - 22F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
427-891-015	HF55 HMEF with Smoothbore Catheter Mount 15cm with Ported Swivel Elbow 22F	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
429-203-020	Hygrovent S Bacterial Viral HMEF Small + Smoothbore Catheter Mount 20cm with Ported Swivel Elbow 15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
430-201-010	Hygrovent S Bacterial Viral HMEF Small + Smoothbore Catheter Mount 10cm with Ported Swivel Elbow 15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
430-201-015	Hygrovent S Bacterial Viral HMEF Small + Smoothbore Catheter Mount 15cm with Ported Swivel Elbow 15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N
430-203-015	Hygrovent S Bacterial Viral HMEF Small with Smoothbore Catheter Mount 15cm with Swivel Elbow 15M	Class Ila (Rule 2)	61134	Heat/moisture exchanger/microbial filter, sterile	N

435-355-015	Hygrovent 5 Bacterial Viral HMEF Small with Straight Catheter Mount 15F-22M/15M	Class Ila (Rule 2)	61134	Heatmoisture exchanger microbial filter, sterile	N
HP55-FT15	HP55 HMEF with Flex-Lock Straight Catheter Mount 15F-22F	Class Ila (Rule 2)	61134	Heatmoisture exchanger microbial filter, sterile	N

Bacterial/Viral Filter with HME (Non-Sterile) TF, 083

Intended use: A non-sterile device intended to be placed within a breathing circuit proximal to the patient, to remove and retain microbes whilst capturing the patient's exhaled heat and moisture so that they can be used to heat and humidify the therapeutic gases inspired by the patient. It is typically a plastic housing which contains both a bidirectional microbial filter, intended to reduce the risk of cross-contamination between patients, and a heatmoisture exchanger (HME), intended to maintain the mucous membranes of the respiratory tract. It is typically used during anaesthesia or periods of prolonged respiratory support/therapy. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
Bacterial/Viral Filter					
038-41-350	ThermoShield Adult Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-350U	ThermoShield Adult Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-330	ThermoShield Adult Angled Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-330U	ThermoShield Adult Angled Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-350/305	ThermoShield Adult Bacterial Viral HMEF with Catheter Mount with Swivel Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-350/322	ThermoShield Adult Bacterial Viral HMEF with Smoothbore Low Profile Elbow Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-350/440	ThermoShield Adult Bacterial Viral HMEF with Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355 INA	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355U	ThermoShield Adult Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/306	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Catheter Mount with Swivel Elbow W/ Cap	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/326U	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Smoothbore Catheter Mount Swivel Elbow W/ Cap	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/310	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/310U	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/310/440	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount + Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/310/643	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Cath Mount + Swivel Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/301	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Standard Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/301U	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Standard Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N

038-41-355/302	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Catheter Mount with Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/311	ThermoShield Adult Bacterial Viral HMEF with Luer Port + 22F/15F Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/311A	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount + Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/312	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Catheter Mount with Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/315	ThermoShield HMEF Luer Port Flex Cath Mount D/ Swivel Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/315U	ThermoShield HMEF Luer Port Flex Cath Mount D/ Swivel Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/317	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/317SR	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/317/440	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Flex-Lock Catheter Mount + Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/640	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-335	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-335U	ThermoShield Adult Angled Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355L3	LuerSafe Adult Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355L3U	LuerSafe Adult Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355L3U	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355L3U	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355/326	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Smoothbore Catheter Mount Swivel Elbow W/ Cap	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-355	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-306W	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Low Profile Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-350/311	ThermoShield Adult Bacterial Viral HMEF with Luer Port + 22F/15F Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-357	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Low Profile Elbow Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-357L3	LuerSafe ThermoShield Adult HMEF with Self-Sealing Luer Port + Catheter Mount with Elbow	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-359	ThermoShield Adult Bacterial Viral HMEF with Luer Port Swivel Elbow W/ Cap Flex-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
038-41-369	Oxygen / Nitrous Oxide Circuit Mouthpiece with ThermoShield Bacterial Viral HME Filter	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N

301-100-000	Hygrovent Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
301-100-000U	Hygrovent Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-020-001	Hygrovent Gold Basic WFL	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-000-000NS	Hygrovent Gold Basic (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-001-010ENS	Hygrovent Gold Comfort (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-005-010ENS	Hygrovent Gold Standard Flex (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-021-010FNS	Hygrovent Gold Comfort WFL (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-031-010ANS	Hygrovent Gold Comfort Plus (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
355-105-015FNS	Hygrovent Gold Standard Flex (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
352-215-010ONS	HME-Booster T-Piece WFL Kit 3 (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
354-200-000NS	HME-Booster T-Piece with Hygrovent 5 Bacterial Viral HMEF Small (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
354-205-010NS	HME-Booster T-Piece Kit 2 (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
354-215-010NS	HME-Booster T-Piece Kit 1 (Non-Sterile)	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-020-001U	Hygrovent Gold Basic WFL	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-000-000B	Hygrovent Gold Basic	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-000-000U	Hygrovent Gold Basic	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-000-010U	Hygrovent Gold Comfort	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-001-010B	Hygrovent Gold Comfort	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-001-010U	Hygrovent Gold Comfort	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-005-010B	Hygrovent Gold Standard	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
356-005-010U	Hygrovent Gold Standard	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
362-000-000U	HME-Booster T-Piece with WFL	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
362-200-000	HME-Booster T-Piece WFL + Hygrovent 5 HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N
362-200-000U	HME-Booster T-Piece WFL + Hygrovent 5 HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/ microbial filter, non-sterile	N

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364-221-010U	HME-Booster T-Piece WFL Kit 7 with 3 X HMEF and Catheter Mount	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
364-222-000U	HME-Booster T-Piece WFL Kit 6 with 3 X HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
HF055	HF55 Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
Bacterial/Viral Filter Mini					
038-42-350	ThermoShield Mini Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-350U	ThermoShield Mini Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-350/640	ThermoShield Mini Bacterial Viral HMEF + Low Profile Elbow	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355/94A	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355U	ThermoShield Mini Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355W	ThermoShield Mini Bacterial Viral HMEF with Screw Cap Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355L8	LuerSafe Mini Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355/301	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Standard Catheter Mount	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-356	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-356U	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355/311	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Flexi-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355/311U	ThermoShield Mini Bacterial Viral HMEF with Luer Port and Flexi-Lock Catheter Mount	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-356L3	LuerSafe Mini Bacterial Viral HMEF with Self-Sealing Luer Port and Low Profile Elbow 22M/15F	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-357	ThermoShield Mini Bacterial Viral HMEF with Luer Port Swivel Elbow W/Cap F-L Catheter Mount	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-43-355	ThermoShield Neonatal Bacterial Viral HMEF with Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-43-355U	ThermoShield Neonatal Bacterial Viral Filter and HME with Luer Port	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-43-355F	ThermoShield Neonatal Bacterial Viral Filter and HME with Luer Port with Serial Label	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-200-000	Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-200-000U	Hygrovent S Bacterial Viral HMEF Small	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-210-000	Hygrovent S Angled Bacterial Viral HMEF Small	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N

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301-210-000U	Hygrovent S Angled Bacterial Viral HMEF Small	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-510-000	Hygrovent Child Angled Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-510-000U	Hygrovent Child Angled Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-520-000	Hygrovent Child Straight Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
301-520-000U	Hygrovent Child Straight Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
354-221-000	Booster T-Piece Kit 5	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
354-231-020	HME-Booster T-Piece Kit 4	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
459-204-000	Hygrovent S Bacterial Viral HMEF Small with Flexi-Lock Catheter Mount with Elbow 15F-22M/15M	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N



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Infant Nasal CPAP (Single Use, Sterile)

TF: 084

Intended use: A non-sterile, semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient, and held in place with a head strap, to deliver oxygen (O₂) to the patient and provide continuous positive airway pressure (CPAP) from the devices to which it is connected. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
038-13-100	Infant Nasal CPAP Cannula Set Size 00	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-110	Infant Nasal CPAP Cannula Set Size 0	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-111	Infant Nasal CPAP Cannula Set Size 1	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-112	Infant Nasal CPAP Cannula Set Size 2	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-113	Infant Nasal CPAP Cannula Set Size 3	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-114	Infant Nasal CPAP Cannula Set Size 4	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-115	Infant Nasal CPAP Cannula Set Size 5	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-200	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 00	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-210	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 0	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-211	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 1	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-212	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 2	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-213	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 3	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-214	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 4	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N
038-13-215	Infant Nasal CPAP Cannula Kit with Breathing Tubes Size 5	Class Ila (Rule 5)	35202	CPAP nasal oxygen cannula	N

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Heat and Moisture Exchangers (HMEs) (Sterile and Non-sterile)

TF: 085

Intended use: A one-piece, canister-like device that connects in-line with a patient's artificial airway (e.g., an endotracheal (ET) tube), to capture the patient's exhaled heat and moisture so that they can be used to heat and humidify therapeutic gases inspired by the patient. It does not include a microbial filter. Commonly known as a heat & moisture exchanger (HME) or an "artificial nose", it is used when the patient is subjected to extended periods of breathing dry gases such as during anaesthesia or intensive care ventilation. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
Non-Sterile					
038-41-250	ThermoTrach Tracheostomy HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-250F	ThermoTrach HME with 15mm Connector Swivel Oxygen Port and Cough Vent	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-250T	ThermoTrach Tracheostomy HME with Vent Swivel Oxygen Port and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-250TU	ThermoTrach Tracheostomy HME with Vent Swivel Oxygen Port and 2.1m Oxygen Tubing	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-250U	ThermoTrach Tracheostomy HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-255	ThermoTrach Tracheostomy Low Resistance HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-260	ThermoTrach Tracheostomy Low Resistance HME with Vent	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-260U	ThermoTrach Tracheostomy Low Resistance HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-600-000	Climavent S HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-600-000U	Climavent S HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-605-000	Climavent S Angled HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-605-000U	Climavent S Angled HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-610-000	Climavent HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-610-000U	Climavent HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-621-000	Climavent Child Angled HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-621-000U	Climavent Child Angled HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-622-000	Climavent Child Straight HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-622-000U	Climavent Child Straight HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-630-000	Climavent XS HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N

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301-630-000U	Climavent XS HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-640-000	Climavent XS Angled HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-640-000U	Climavent XS Angled HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-700-000	Climatrach Tracheostomy HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-700-000U	Climatrach Tracheostomy HME Standard	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-710-000	Climatrach Tracheostomy HME with Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-710-000U	Climatrach Tracheostomy HME with Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-720-000	Climatrach Tracheostomy HME with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-720-000U	Climatrach Tracheostomy HME with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-730-000	Climatrach Tracheostomy HME with Oxygen Port with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
301-730-000U	Climatrach Tracheostomy HME + Oxygen Port + Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
Sterile					
038-41-250STR	ThermoTrach Tracheostomy HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-255STR	ThermoTrach Tracheostomy Low Resistance HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-260STR	ThermoTrach Tracheostomy Low Resistance HME with Vent	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-43-150	Neonatal HME Sterile	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-43-150 BRZ	Neonatal HME Sterile	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-600-000	Climavent S HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-605-000	Climavent S Angled HME Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-610-000	Climavent HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-621-000	Climavent Child Angled HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-622-000	Climavent Child Straight HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-630-000	Climavent XS HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-640-000	Climavent XS Angled HME Extra Small	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-700-000	Climatrach Tracheostomy HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N

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300-700-009 BRZ	Climatrach Tracheostomy HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-700-000U	Climatrach Tracheostomy HME	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-710-000	Climatrach Tracheostomy HME with Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-710-000U	Climatrach Tracheostomy HME with Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-730-000	Climatrach Tracheostomy HME with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-730-000	Climatrach Tracheostomy HME with Oxygen Port and Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-730-006 BRZ	Climatrach Tracheostomy HME with Oxygen Port and Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-730-000U	Climatrach Tracheostomy HME with Oxygen Port with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N



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Video Stylet (Sterile)

TF: 109a

Intended use: The ProVu Video Stylet (ProVu VS) is a sterile, single-use, video-enabled stylet and ETT intubation system with malleable and directional control intended to assist with oral and nasal intubations and designed for use in adults. The device consists of a control wheel at the proximal end and an incorporated light source and video camera at the distal end. The ProVu VS is connected to a ProVu Display to provide a video stream from the distal end of the ETT.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
038-000-085	ProVu Single Use Video Stylet with ET Tube Size 6.5	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-070	ProVu Single Use Video Stylet with ET Tube Size 7.0	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-075	ProVu Single Use Video Stylet with ET Tube Size 7.5	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-080	ProVu Single Use Video Stylet with ET Tube Size 8.0	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y

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Classic - Intermittent Urinary Catheters (Sterile)

TF: 117

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

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
WyCath Uncoated Intermittent Catheter Male - Soft Tip					
U4SM10	WyCath Uncoated Intermittent Catheter 4 Eyelet Soft Tip 40cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
U4SM12	WyCath Uncoated Intermittent Catheter 4 Eyelet Soft Tip 40cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
U4SM14	WyCath Uncoated Intermittent Catheter 4 Eyelet Soft Tip 40cm 14CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
U4SM16	WyCath Uncoated Intermittent Catheter 4 Eyelet Soft Tip 40cm 16CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USM10	WyCath Uncoated Intermittent Catheter Soft Tip 40cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USM12	WyCath Uncoated Intermittent Catheter Soft Tip 40cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USM14	WyCath Uncoated Intermittent Catheter Soft Tip 40cm 14CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USM16	WyCath Uncoated Intermittent Catheter Soft Tip 40cm 16CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Male - Taper Tip					
UTAM10	WyCath Uncoated Intermittent Catheter Tapered Tip 40cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAM12	WyCath Uncoated Intermittent Catheter Tapered Tip 40cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAM14	WyCath Uncoated Intermittent Catheter Tapered Tip 40cm 14CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAM16	WyCath Uncoated Intermittent Catheter Tapered Tip 40cm 16CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Female - Taper Tip					
UTAF10	WyCath Uncoated Intermittent Catheter Tapered Tip Female 18cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAF12	WyCath Uncoated Intermittent Catheter Tapered Tip Female 18cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAF12	WyCath Uncoated Intermittent Catheter Tapered Tip Female 18cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Female - Soft Tip					
USF08	WyCath Uncoated Intermittent Catheter Soft Tip Female 18cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USF10	WyCath Uncoated Intermittent Catheter Soft Tip Female 18cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
USF12	WyCath Uncoated Intermittent Catheter Soft Tip Female 18cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Paediatric - Standard Tip					
UP06	WyCath Uncoated Intermittent Catheter Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UP08	WyCath Uncoated Intermittent Catheter Paediatric 30cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UP10	WyCath Uncoated Intermittent Catheter Soft Tip Paediatric 30cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UP12	WyCath Uncoated Intermittent Catheter Soft Tip Paediatric 30cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Paediatric - Taper Tip					
UTP06	WyCath Uncoated Intermittent Catheter Tapered Tip Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTP08	WyCath Uncoated Intermittent Catheter Tapered Tip Paediatric 30cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTP10	WyCath Uncoated Intermittent Catheter Tapered Tip Paediatric 30cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTP12	WyCath Uncoated Intermittent Catheter Tapered Tip Paediatric 30cm 12CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N

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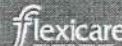
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038-990-065U	VentSeal HVLP Cutfed Reinforced ET Tube ID Size 6.5mm with Stylet	Class IIA (Rule 5)	46569	Reinforced Endotracheal Tube, Single use Reinforced	N
038-990-070U	VentSeal Reinforced ET Tube ID 7.0 + Stylet + Sterile	Class IIA (Rule 5)	46568	Endotracheal Tube, Single use Reinforced	N
038-990-075U	VentSeal HVLP Cutfed Reinforced ET Tube ID Size 7.0mm with Stylet	Class IIA (Rule 5)	46563	Endotracheal Tube, Single use Reinforced	N
038-990-075J	VentSeal Reinforced ET Tube ID 7.5 + Stylet + Sterile	Class IIA (Rule 5)	46569	Endotracheal Tube, Single use Reinforced	N
038-990-080U	VentSeal Reinforced ET Tube ID 8.0 + Stylet + Sterile	Class IIA (Rule 5)	46569	Endotracheal Tube, Single use Reinforced	N
038-990-080U	VentSeal HVLP Cutfed Reinforced ET Tube ID Size 8.0mm with Stylet	Class IIA (Rule 5)	46568	Endotracheal Tube, Single use Reinforced	N
038-990-085J	VentSeal Reinforced ET Tube ID 8.5 + Stylet + Sterile	Class IIA (Rule 5)	46569	Endotracheal Tube, Single use Reinforced	N
038-990-085U	VentSeal HVLP Cutfed Reinforced ET Tube ID Size 8.5mm with Stylet	Class IIA (Rule 5)	46569	Endotracheal Tube, Single use Reinforced	N
038-990-090U	VentSeal HVLP Cutfed Reinforced ET Tube ID Size 9.0mm with Stylet	Class IIA (Rule 5)	46569	Endotracheal Tube, Single use Reinforced	N



012-10-670	DualGuard Adult Endoscopy Mouthpiece 4.25m O2 Delivery/CO2 Monitoring, Filter, Microstream Type Luer	Class IIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-870U	DualGuard Adult Endoscopy Mouthpiece 14ft O2 Delivery/CO2 Monitoring, Filter, Microstream Type	Class IIa (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N

Endoscopic Bite Block (Non-sterile, single use)

TF: 124

Intended use: A non-sterile, oral bite block featuring a semi-rigid tube with nasal prongs designed to be inserted into the nostrils of a patient, and held in place with a head strap, to simultaneously deliver oxygen (O2) and allow sampling of exhaled gas for carbon dioxide (CO2) monitoring through separate prongs. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	QMDN CODE	QMDN TERM	RHQS APPLIES Y/N
032-10-828	DualGuard Endoscopy Mouthpiece Adult 2m Combined O2 Delivery/CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-845	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-850	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-850U	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-855	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-855U	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-860	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-860U	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Female Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-865	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-865U	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Male Luer	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-868	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Luer Slip	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N
032-10-868U	DualGuard Endoscopy Mouthpiece Adult 3m Combined O2 Delivery/CO2 Monitoring Filter with Luer Slip	Class I(a) (Rule 5)	36306	Carbon-dioxide-sampling nasal oxygen cannula	N

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Suction Yankauers (Sterile)

TF: 129

Intended use: Suction Yankauers are rigid catheters intended to be used in conjunction with suction tubing and equipment to facilitate medical suction of bodily fluids and material (e.g., of the oropharyngeal cavity) without aspiration of the surrounding tissue. The products are intended to be used for clinical applications by trained personnel. The device design includes straight tip (with and without vacuum control) or rosebud tip (with and without vacuum control). Flexicare Suction Yankauers are supplied sterile and intended for single use only.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
050-35-001	Suction Yankauer with Straight Tip and Vacuum Control Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-002	Suction Yankauer with Straight Tip Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-003	Suction Yankauer with Rosebud Tip and Vacuum Control Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-003ST	Suction Yankauer with Rosebud Tip and Vacuum Control Sterile with 2m Suction Tube	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-003T	Suction Yankauer with Rosebud Tip and Vacuum Control with Suction Tube 3m F/P Connector 7mm Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-004	Suction Yankauer with Rosebud Tip Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-004A	Suction Yankauer with Rosebud Tip and Vacuum Control with Suction Tube 3m Green F/P Connector 6mm	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-004B	Suction Yankauer with Rosebud Tip and Vacuum Control with Suction Tube 4.5m Green F/P Connector 6mm	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-004C	Suction Yankauer with Rosebud Tip and Vacuum Control with Suction Tube 6m Green F/P Connector 6mm	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-010	Standard Suction Yankauer Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N
050-35-011	Standard Suction Yankauer with Vacuum Control Sterile	Class Ila (Rule 5)	16779	Suction system tubing, single-use	N

Respiratory Humidifier (Non-Sterile)

TF: 132

Intended use: A mains electricity (AC-powered) device designed to heat and humidify air/moxygen inspired by a patient to help maintain the mucous membranes of the respiratory tract typically during periods of prolonged respiratory support/therapy (e.g., mechanical ventilation, BPAP/CAPAP therapy). The heated/humidified gases are delivered to the patient's airway and lungs via the nose/mouth or a tracheostomy in association with a patient respiratory device (e.g., ventilator, BPAP/CAPAP unit). The humidifier typically includes a heating element and provisions for attaching a humidification chamber and tubing set.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
FL9000	Respiratory Humidifier Heater - UK Plug with 2 Pin Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000EU	Respiratory Humidifier European 230V with 2 Pin Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000U	Respiratory Humidifier USA 110-115V with NEMA 5-15P 3 Pin Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000 AUS	Respiratory Humidifier Heater - with 3 Pin Australia Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000 INDIA	Respiratory Humidifier Heater - 240 Volt 3Pin Round Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-01	Respiratory Humidifier Single Heated Wire Humidifier Adapter Lead	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-01U	Respiratory Humidifier Single Heated Wire Humidifier Adapter Lead	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-02	Respiratory Humidifier Dual Heated Wire Humidifier Adapter Lead	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-02U	Respiratory Humidifier Dual Heated Wire Humidifier Adapter Lead	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-03	Respiratory Humidifier Temperature Probe Lead 1.5m	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-03U	Respiratory Humidifier Temperature Probe Lead 1.5m	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-04	Respiratory Humidifier Single Use Temperature Probe	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-04STR	Respiratory Humidifier Single Use Temperature Probe (Sterile)	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
FL9000-04U	Respiratory Humidifier Single Use Temperature Probe	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 930 400	HME Booster Heater EU	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 931 400	HME Booster Heater UK	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 932 400	HME Booster Heater with US Plug	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 933 400	HME Booster Heater US	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 934 400	HME Booster Heater AUS	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y
358 930 400K	HME Booster Heater Korea	Class Iib (Rule 9)	12050	Heated respiratory humidifier	Y



Pocket Resuscitation Mask (Non-Sterile, Single Use)

TF: 143

Intended use: A flexible, form-shaped device that is placed over a patient's mouth to administer "mouth-to-mask" exhaled air from the user to the patient during cardiopulmonary resuscitation (CPR). The device is designed to replace "mouth-to-mouth" resuscitation therefore reducing the risk of cross-contamination; it is also used on manikins by students during CPR training. The device typically consists of the mask with a mouthpiece and a non-breathing valve and/or bacteria filter. Also referred to as a pocket face mask, it is typically used by emergency medical services (EMS) or as part of first aid kits. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
010-909	Pocket First Aid Resuscitation Mask	Class Ila (Rule 2)	61326	Cardiopulmonary resuscitation mask, single-use	N
010-990U	Pocket First Aid Resuscitation Mask	Class Ila (Rule 2)	61326	Cardiopulmonary resuscitation mask, single-use	N

Anaesthetic Face Masks (Non-Sterile)

TF: 146

Intended use: A flexible, form-shaped device designed to be placed over a patient's nose and/or mouth to direct anaesthetic gases to the upper airway. It is made of conductive or non-conductive rubber, polyvinyl chloride (PVC), or other sterilizable materials that produce a soft, flexible cover to create an airtight seal against the patient's face. It typically includes a 22 mm connector (adult) or a 15 mm connector (paediatric), and is available in a range of sizes. It may be stabilized with a head strap. This device is sometimes used in association with a manual resuscitator. This is a single-use device.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDH CODE	GMDH TERM	ROHS APPLIES Y/N
038-51-4003FL	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FLU	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FNF	Anaesthesia Face Mask Single Use Unscented no Hook Ring Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FNP	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FPB	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Large Adult Size 5 + Mini HMEF + Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FPIC	Anaesthesia Face Mask Inflatable Single Use Vanilla Large Adult Size 5 + Mini HMEF + C Mount + 3xElbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FPD	Anaesthesia Face Mask Inflatable Single Use Vanilla Large Adult Size 3 + Mini HMEF + C Mount + Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FPU	Anaesthesia Face Mask Inflatable Single Use - Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4003FV	Anaesthesia Face Mask Inflatable Single Use - Large Adult Size 5 (Green)	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FL	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FLU	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FNF	Anaesthesia Face Mask Single Use Unscented Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FNP	Anaesthesia Face Mask Inflatable Single Use Unscented no Hook Ring Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FPB	Anaesthesia Face Mask Inflatable Single Use - Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-4103FPU	Anaesthesia Face Mask Inflatable Single Use Vanilla Adult Size 4 + Mini HMEF with Luer Port + Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N

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038-53-440SFH	Anaesthesia Face Mask Single Use Unscented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFH	Anaesthesia Face Mask Single Use Unscented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFP	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFPJ	Anaesthesia Face Mask Inflatable Single Use Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFB	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFH	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFPV	Anaesthesia Face Mask Inflatable Single Use Neonatal Size 0 (Green)	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
Pre-filled					
038-51-390	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Extra Large Adult Size 6	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400 INA	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400SFL/INA	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5 and HMEF Filter	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400E	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5 and HMEF Filter	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400G	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5 LIP Elbow Mini B-Filter	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410 INA	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410SFL/INA	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4 + Low Profile Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4 + HMEF with Luer Port	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410E	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4 + HMEF	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415 INA	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415SFL/INA	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Child Size 3	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3 + Mini HMEF + Luer Port	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415E	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3 + Mini HMEF	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420 INA	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420SFL/INA	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Medium Child Size 2	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2 + Mini HMEF + Luer Port	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420E	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2 + Mini HMEF	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430 INA	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N

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038-52-430U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1 with Mini HMEF and Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1 with Mini HMEF	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440SFL/INA	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440U	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0 + Mini HMEF + Elbow	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440B	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0 + Mini HMEF	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-390H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Extra Large Adult Size 6	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-400H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Large Adult Size 5	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-51-410H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Adult Size 4	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-415H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Large Child Size 3	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-420H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Child Size 2	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-52-430H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Small Child Size 1	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
038-53-440H	Anaesthesia Face Mask Pre-Filled Inflatable Single Use No Hook Neonatal Size 0	Class Ila (Rule 2)	46232	Anaesthesia face mask, Single Use	N
Reusable					
038-51-400SIL	Anaesthesia Face Mask Silicone Reusable Large Adult Size 5	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-400SILU	Anaesthesia Face Mask Silicone Reusable Large Adult Size 5	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-400SILX	Anaesthesia Face Mask Silicone Reusable with Hook Large Adult Size 5	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-410SIL	Anaesthesia Face Mask Silicone Reusable Adult Size 4	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-410SILU	Anaesthesia Face Mask Silicone Reusable Adult Size 4	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-410SILX	Anaesthesia Face Mask Silicone Reusable Adult Size 4 with Hook	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-415SIL	Anaesthesia Face Mask Silicone Reusable Large Child Size 3	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-420SIL	Anaesthesia Face Mask Silicone Reusable Medium Child Size 2	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-430SIL	Anaesthesia Face Mask Silicone Reusable Small Child Size 1	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-430SILU	Anaesthesia Face Mask Silicone Reusable Small Child Size 1	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-53-440SIL	Anaesthesia Face Mask Silicone Reusable Neonatal Size 0	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
Anaesthesia Face Mask packs					
038-51-400A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5+Elbow+HMEF with Luer Port	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-410A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4 + HMEF with Luer Port + Elbow	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-415A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3 + Mini HMEF + Elbow	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-420A	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2 + Mini HMEF + Elbow	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-52-430A	Anaesthesia Face Mask Pack with Detachable Elbow + HMEF + Catheter Mount Size Large Adult 6	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-355	Anaesthesia Face Mask Pack with Detachable Elbow + HMEF + Catheter Mount Size Large Adult 5	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-51-354	Anaesthesia Face Mask Pack with Detachable Elbow + HMEF + Catheter Mount Adult Size 4	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N

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038-61-353	Anaesthesia Face Mask Pack with Detachable Elbow + Mini HMEF + Catheter Mount Size Large Child 3	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-61-352	Anaesthesia Face Mask Pack with Detachable Elbow + Mini HMEF + Catheter Mount Medium Child Size 2	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N
038-61-351	Anaesthesia Face Mask Small Child Size 1 with Detachable Elbow + Mini HMEF + Catheter Mount	Class Ila (Rule 2)	35176	Anaesthesia face mask, reusable	N

Stoma Plug (Sterile)

TF: 150

Intended use: A sterile plug-like device intended to be placed in an intestinal and/or urinary stoma to prevent leakage and narrowing (stenosis), typically during intermittent use of an enema catheter/tube. It is in the form of a flanged cylinder and is made of flexible synthetic polymer materials (e.g., silicone). This is a single-patient reusable device after appropriate cleaning/disinfection.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
WS0310	Wystopper Stoma stopper 3cm size 10ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0312	Wystopper Stoma stopper 3cm size 12ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0314	Wystopper Stoma stopper 3cm size 14ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0316	Wystopper Stoma stopper 3cm size 16ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0610	Wystopper Stoma stopper 6cm size 10ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0612	Wystopper Stoma stopper 6cm size 12ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0614	Wystopper Stoma stopper 6cm size 14ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N
WS0616	Wystopper Stoma stopper 6cm size 16ch	Class Ila (Rule 5)	62183	Intestinal/urinary stoma button	N

Meditera Breathing Circuits

TF: 154

Intended use: Meditera Breathing Circuits deliver medical gases and vapours, and oxygenation to the patient for general anaesthesia, mechanical ventilation and ventilatory support. These devices are used by trained medical professionals for the duration of the procedure on neonatal, paediatric, or adult patients.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
5016A112	Neonatal breathing circuit for anaesthesia, 10mm, 150cm	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5016DA151	Breathing circuit 22mm 180cm with swivel Y-piece	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5016DA156	Breathing circuit 22mm 200cm, water traps	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017A1003	Anaesthesia circuit 15mm, 170cm, 1L breathing bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017A127	Anaesth. set UKE 22mm, 105-137cm vario, 2L breathing bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017A156	Breathing circuit 22mm, 200cm, PE	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

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5017A412	Anaesth. set 15mm 55-180cm vario, tube 120cm, 1L breathing bag	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017A436	Anaesthesia set 22mm 95-115cm vario, 2L breathing bag, elbow with LL, latex free	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017DA126	Anaesthesia set 22mm 180cm, elbow, 2L breathing bag, LF	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
5017DA129	Anaesthesia set 22mm 200cm, water traps, 2L breathing bag, LF	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-352	Breathing bag set 22mm, 120cm spiral tubing, 2L	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-312	CPAP system 22mm, 200cm, EVA	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-40091	Corrugated tubing 22mm, 50cm, EVA, non sterile	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-40120	Corrugated tubing 22mm, 120cm, PE, non sterile	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-40180	Corrugated tubing 22mm, 200cm, PE	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-520	Breathing bag set 22mm, 90-245cm vario, 2L, latex free	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
8-735	Breathing bag set 22mm, 35-112cm vario, 2L, latex free	Class Ila (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N



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DOC-000003-Declaration of Conformity for Class IIa IIb Devices

Final Audit Report

2023-07-26

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Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Canula Nazala de Flux Inalt	Flexicare	Pentru Oxigenoterapie	
2		Sistem de aspirație cu circuit închis	Flexicare	14Fr, Endotraheal	
3		Sistem de aspirație cu circuit închis	Flexicare	16Fr, Endotraheal	
4		Tub conector tip Y	Flexicare	d-22 mm	
5		Masca respiratoare pentru maturi	Flexicare	Nr.3	
6		Masca respiratoare pentru maturi	Flexicare	Nr.4	
7		Masca respiratoare pentru maturi	Flexicare	Nr.5	
8		Masca respiratoare pentru maturi	Flexicare	Nr.6	
9		Sistem de aspirație cu circuit închis	Flexicare	P/u Traheostomie	

