

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

Semnătura _____



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;


<p>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.</p>	<p>Intermittent catheters; Urine drainage bags;</p> 
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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.

SGS

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
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Mobile: +41 79 731 49 32
Email: virginie.siloret@sgs.com



SGS



SGS Belgium NV

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Member of the SGS Group

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



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
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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 - Single Use (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.

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, OMDN CODE, OMDN TERM, ROHS APPLIES Y/N. Lists various resuscitator bags and packs.

Resus Bags - Reusable (Non-Sterile)

TF: 025b

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.

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, OMDN CODE, OMDN TERM, ROHS APPLIES Y/N. Lists various resuscitator bags and packs.

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, OMDN CODE, OMDN TERM, ROHS APPLIES Y/N. Lists various resuscitator bags and packs.



Table with columns: Product Code, Product Description, Classification Under Annex IX, GMDH Code, GMDH Term, and RoHS Applies Y/N. Contains various models of adult and pediatric non-rebreathing masks.

Cluster headaches Kits

GOP05-F02 Issue No: 1

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Table with columns: Product Code, Product Description, Classification Under Annex IX, GMDH Code, GMDH Term, and RoHS Applies Y/N. Contains models for cluster headaches.

Aerosol Masks, Venturi Masks & Venturi Barrels (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.

Table with columns: Product Code, Product Description, Classification Under Annex IX, GMDH Code, GMDH Term, and RoHS Applies Y/N. Contains various models of aerosol masks, venturi masks, and venturi barrels.

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Table with columns: Product Code, Product Description, Classification Under Annex IX, GMDH Code, GMDH Term, and RoHS Applies Y/N. Contains various models of multi-venturi masks.

GOP05-F02 Issue No: 1

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Table with columns: Product Code, Product Description, Classification Under Annex IX, GMDH Code, GMDH Term, and RoHS Applies Y/N. Contains various models of single-venturi masks (adults).

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EC Declaration of Conformity



Table with columns: Product Name, Class, Rule, CE Mark, Description, and Conformance. Rows include various Adult Venturi Fixed Concentration Masks (e.g., 033-10-008, 033-10-009, etc.)

EC Declaration of Conformity



Table with columns: Product Name, Class, Rule, CE Mark, Description, and Conformance. Rows include various Adult Venturi Fixed Concentration Masks (e.g., 033-10-042T, 033-10-042T1, etc.)



EC Declaration of Conformity



Table with columns: Product Name, Class, Rule, CE Mark, Description, and Conformance. Rows include various Paediatric Venturi Fixed Concentration Masks (e.g., 033-10-048CT, 033-10-048CT1, etc.) and Single Venturi Masks (e.g., 032-10-050, 032-10-050C, etc.)

EC Declaration of Conformity



Table with columns: Product Name, Class, Rule, CE Mark, Description, and Conformance. Rows include various Paediatric Venturi Fixed Concentration Masks (e.g., 032-10-053C, 032-10-053CT, etc.)

Parallel Circuits - 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/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.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Rows include items like 038-01-100, 038-01-100J, 038-01-100K, etc.

GOP025-F02 Issue 1

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Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Rows include items like 038-01-105, 038-01-105A, 038-01-105B, etc.

GOP025-F02 Issue 1

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Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Rows include items like 038-01-1231, 038-01-1232, 038-01-1233, etc.

GOP025-F02 Issue 1

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Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Rows include items like 038-01-1101, 038-01-110X, 038-01-110Y, etc.

GOP025-F02 Issue 1

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EC Declaration of Conformity



Table with columns for EC Declaration of Conformity, listing various medical device models and their specifications.

EC Declaration of Conformity



Table with columns for EC Declaration of Conformity, listing various medical device models and their specifications.



EC Declaration of Conformity



Table with columns for EC Declaration of Conformity, listing various medical device models and their specifications.

EC Declaration of Conformity



Table with columns for EC Declaration of Conformity, listing various medical device models and their specifications.

EC Declaration of Conformity



EC Declaration of Conformity



Table with 5 columns: Part Number, Description, Class, Rule, and CE Mark. Contains 100 rows of medical device specifications.

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EC Declaration of Conformity



EC Declaration of Conformity



Table with 5 columns: Part Number, Description, Class, Rule, and CE Mark. Contains 100 rows of medical device specifications.

Table with 5 columns: Part Number, Description, Class, Rule, and CE Mark. Contains 100 rows of medical device specifications.



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
038-01-100353STR	Parallel Circuit 1.6m 22mm with Y-Piece and ThermoShield HMEF with CO ₂ Port	Class IIa (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 IIa (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 IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1005402STR	Parallel Circuit 1.6m 22mm with Y-Piece and Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10215TR	Parallel Circuit 1.6m 22mm with Swivel Y-Piece Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1009415TR	Parallel Circuit 1.6m 22mm with Y-Piece and Low Profile Elbow with Luer Lock Port	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10633TR	Flexi-Lock Parallel Circuit - 0.7m to 2.0m with Y-Piece & HMEF (Sterile)	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-122F5TR	Parallel Circuit 3.0m 22mm Swivel Y-Piece Luer Elbow & 3.0m Limb and 2L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-122H5TR	Parallel Circuit 1.8m 22mm Swivel Y-Piece 1.8m Blue Limb LP Elbow with Luer and 2L Res Bag Kit 5	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1093TR	Parallel Circuit 1.6m 22mm with Y-Piece	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1193TR	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
038-01-110KS	Parallel Circuit 1.6m 22mm with Y-Piece 1.2m Limb LP/Elbow + HMEF + 3L Res Bag 3m Min Line Sterile	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1193S9S	Parallel Circuit 1.6m 0.8m Limb LP Elbow HMEF 2L Res Bag + F-L Catheter Mount with Swivel Elbow	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-119415TR	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

038-01-1205TR	Parallel Circuit 1.5m 22mm with Y-Piece and 0.8m Limb	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Flexi-Lock Circuits					
038-01-1009365STR	Flexi-Lock Parallel Circuit - 0.7m to 2.0m with 1.5m Flexi-Lock Limb and SV Filter	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11643TR	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1164STRJ	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11655TR	Flexi-Lock Parallel Circuit - 0.75m to 2.0m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11665TR	Flexi-Lock Parallel Circuit - 0.8m to 1.5m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11668TRJ	Flexi-Lock Parallel Circuit - 0.8m to 1.5m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11675TR	Flexi-Lock Parallel Circuit - 0.8m to 1.5m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11685TR	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11685TRJ	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Mini HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-11695TR	Flexi-Lock Parallel Circuit - 1.1m to 3.0m with Y-Piece with Elbow Large HMEF and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-8145TR	Adult Exp Circuit 95° Y-Piece Luer Elbow Bacterial Viral Filter Mask 3L Res Bag & M/Low (Sterile)	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-04-451	Adult Hygrovent Gold WFL Breathing System 2.4m Kit 1	Class IIa (Rule 2)	61134	Heatmoisture 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 IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1045STRJ	Smoothbore Circuit 1.6m 22mm with Y-Piece and Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10415TR	Smoothbore Circuit 1.6m 22mm with Y-Piece with Elbow and 3L Reservoir Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1043STR	Smoothbore Circuit 3.0m 22mm with Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-104X5TR	Smoothbore Circuit 1.8m 22mm with Y-Piece and Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-01-104D5TR	Smoothbore Circuit 1.6m 22mm Y-Piece 1.6m Limb Low Profile Elbow with 2L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10425TR	Smoothbore Circuit 1.2m 22mm with Y-Piece and Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10445TR	Smoothbore Circuit 2.1m 22mm with Flexible 22mm F Connectors and 2.1m Smoothbore Limb and 2L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10455TR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF Luer and Smoothbore Catheter Mount DSE with 22F Conn	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10465TR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF w/o Luer & Smoothbore Catheter Mount DSE with 15M Conn	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10475TR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF Luer and Smoothbore Catheter Mount DSE with 22F Conn	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-10485TR	Smoothbore Circuit 1.6m 22mm Y-Piece with HMEF w/o Luer & Smoothbore Catheter Mount DSE with 22F Conn	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-1075TR	Smoothbore Circuit 2.1m 22mm with Y-Piece and Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-01-155B43TR	Smoothbore Circuit 2.4m 22mm + HME Filter + 3.5m Monitoring Line + Swivel Elbow Catheter Mount 15cm	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-16633TR	Smoothbore Circuit 3.0m 15mm with Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-16645TR	Smoothbore Circuit 4.0m 15mm with Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
550-431-150J	Smoothbore Circuit 1.5m 22mm-Hygrovent S HMEF+Flexi-Lock Swivel Cath Mount+Flexible 22F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Paediatric Basic Parallel					
038-02-165415TR	Paediatric Parallel Circuit 1.5m with Luer Elbow	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-1105TR	Paediatric Parallel Circuit 1.5m with Y-Piece 0.8m Limb Low Profile Elbow and 1L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-110415TR	Paediatric Parallel Circuit 1.5m with Y-Piece 0.8m Limb Elbow with Luer Port and 1L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165357S	Paediatric Parallel Circuit 1.5m Kit 1	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165386S	Paediatric Parallel Circuit 1.5m Kit 2	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165910357S	Paediatric Parallel Circuit 1.5m Kit 4	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N

038-02-165910B5TR	Paediatric Parallel Circuit 1.8m with 0.8m x 22mm Tube Limb and 1L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165015TR	Paediatric Parallel Circuit 2.0m with 2.0m 15mm Tube Limb with 22mm F Connectors and 1L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-165025TR	Paediatric Parallel Circuit 2.0m with 2.0m 15mm Tube Limb with 22mm F Connectors and 0.5L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-11045TR	Paediatric Parallel Circuit 1.8m with Y-Piece 0.8m Limb Low Profile Elbow and 1L Res Bag	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Paediatric Flexi-Lock Circuits					
038-02-180KSA	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 5	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-180KSB	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 6	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-160K3	Paediatric Flexi-Lock Parallel Circuit 0.5m to 1.6m Kit 4	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Paediatric Smooth Bore					
038-02-16655TR	Paediatric Smoothbore Circuit 1.8m 15mm with Y-Piece and Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
038-02-166C5TR	Paediatric Smoothbore Circuit 1.8m 15mm with Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Neonatal Smooth Bore					
038-01-1045TR	Neonatal Smoothbore Circuit 1.5m 10mm with Flexible 22mm F Connectors	Class IIa (Rule 2)	37704	Anaesthesia breathing circuit, single-use	N
Corrugated Circuits					
038-04-450	Adult Hygrovent Gold WFL Breathing System 1.8m Kit 1	Class IIa (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 workstation to the patient...

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Rows include various Mapleson circuits like Ayres T-Piece, Adult Bain System, and Infant T-Piece.

Continuation of table from previous page, listing various Mapleson circuits including Bain Coaxial System, Argentic Bain Coaxial System, and Pediatric Mapleson Circuits.

Table listing various Ayres T-Piece, Jackson Rees, and Pediatric Direct systems with columns for product code, description, classification, GMDN code, term, and RoHS status.

Table listing various Mapleson F Ayres T-Pieces and Infant T-Pieces with columns for product code, description, classification, GMDN code, term, and RoHS status.





Table with columns: Part Number, Description, Class, Rule, Code, Product Name, and Status. Includes items like Ventilow Max Coaxial Circuit 2.4m, Argentix Ventilow Max Coaxial Circuit 2.4m, etc.



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 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...

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDH CODE, GMDH TERM, and ROHS APPLIES Y/N. Lists various Intello Plus Adult and Intello Standard Adult kits.



Table with columns: Part Number, Description, Class, Rule, Code, Product Name, and Status. Lists various Intello Basic Adult and Intello Plus Adult kits.



Table with columns: Part Number, Description, Class, Rule, Code, Product Name, and Status. Lists various Intello Basic Adult, Intello Plus Paediatric, and Intello Plus Breathing Circuit kits.

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
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
038-01-959/1 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 Plus 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
038-01-952/2 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
038-03-100	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 Bi-PAP Breathing System 1.6m 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

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 plastic/silicone 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 Maxineo 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 1.6m 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 Kit 6	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-140641	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
038-01-150641	Ventilator Breathing System Adult 1.6m Y-Piece with 2 Ports Luer Elbow + 1 x Water Trap Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
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 & Cash Mount Kit 9	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15512	Ventilator B/Sys 1.6M W/Parts 2 X Traps Insp Limb 1-Piece	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15513	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x Maxineo 1 x HMEF Cash Mount Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15514	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x HMEF & 1 x BV Filter Cash Mount Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15515	Ventilator Breathing System Adult 1.6m 2 x Water Traps 1 x Hepa & 1 x BV Fibers Cash Mount Kit 3	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15515 IN	Ventilator Breathing System Adult 1.6m 2 X Water Traps 1 X Hepa & 1 X BV Fibers Cash 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 + Maxineo 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 + Maxineo Nebuliser Kit 8	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-155376S	Ventilator Breathing System 1.6m Y-Piece with 2 x Ports 2 x Water Traps BV Filter+Cash Mount Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-15535/306	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
038-01-155355/306 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
038-01-155640	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
038-01-155641	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 Traps 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 Seal-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
038-01-2334	Adult Smoothbore Limb 1.8m with 22mm/5mm Connector Plus HepaShield 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

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
038-01-130641STR	Ventilator Breathing System Adult 1.6m Kit with Luer Elbow	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

Bi-PAP Ventilator Breathing Systems (Non-Sterile)
TF: 056b

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	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
038-04-300	Adult CPAP Flex-Lock Breathing System 1.6-4.6m 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 with Mask Filter & SomH2O 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 SomH2O	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 SomH2O	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 BV Filter & SomH2O PEEP Valve	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-946	Adult CPAP Breathing System 1.6m with Mask Filter and SomH2O & 20cmH2O PEEP Valves	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-950	Adult CPAP Single Limb Breathing System 1.6m with Safety Valve	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 2.2m 22mm with Water Trap + 2 x Temperature ports and 3.9m 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

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	OMDN TERM	ROHS APPLIES Y/N
038-35-290	Adult Smoothbore Bi-PAP Breathing System 1.8m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-291	Adult Corrugated Bi-PAP Breathing System 1.8m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292	Adult Smoothbore Bi-PAP Single Limb Breathing System 1.8m with Exhalation Port	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-292A	Adult Smoothbore Single Limb 1.8m 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 1.8m 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 1.8m with Exhalation Valve and Pressure Line	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-294Q	Paediatric Breathing System 1.6m 15mm with Ported Y-Piece + Exhalation Valve + 1.6m Bubble Trapping	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 1.8m with Exhalation Valve and BV 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

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
038-35-300	Adult Smoothbore BiPAP Breathing System 1.8m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-300U	Adult Smoothbore BiPAP Breathing System 1.3m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-300/2U	Adult Smoothbore BiPAP Breathing System 1.3m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-301	Adult Smoothbore BiPAP Breathing System 1.8m and 1 Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-301U	Adult Smoothbore BiPAP Breathing System 1.8m and 1 Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-301/2U	Adult Smoothbore BiPAP Breathing System 1.8m and 1 Filter	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-302	Adult Smoothbore Bi P AP Breathing System 1.6m x 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-302U	Adult Smoothbore Bi P AP Breathing System 1.8m x 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-302/2U	Adult Smoothbore Bi P AP Breathing System 1.8m x 2 Filters	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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	OMDN CODE	OMDN TERM	ROHS APPLIES Y/N
038-01-120A	Bifurcated Smoothbore Circuit 1.8m 22mm with Ported Y-Piece Kit	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-288/1	Smoothbore Single Limb 1.8m 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 1.8m 22mm with Exhalation Valve for Heila 1/4Heila 3 / P4501	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-289	Oasis Circuit 1.8m with Flow Sensor & Exhalation Valve - K0020400	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-357	Smoothbore Single Limb 1.6m 10mm with Exhalation Valve + Flexible 22F Connectors for Medical Standard	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-01-321	Adult Bifurcated Smoothbore Circuit 1.8m 22mm for VS Ultra + Heila VT	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-02-165/842	Paediatric Circuit 1.8m + 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 1.8m + Leak Valve + San-Vent 3V/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	Paediatric Parallel Breathing System 1.8m 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 1.8m 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 1.8m + 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 1.8m + 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 1.8m 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 1.5m + 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 1.8m 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 1.8m 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 1.8m with Exhalation Valve and Flexible 22F Connectors for Elasee	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-297/5	Adult Smoothbore Single Limb 1.8m 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 1.8m 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 1.8m 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 1.8m 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 1.8m + 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 1.8m 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 1.8m with Exhalation Valve and Flexible 22F Connectors Kit 5	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

EC Declaration of Conformity



EC Declaration of Conformity



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

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMON CODE	GMON TERM	ROHS APPLIES Y/N
038-35-069HG	CPAP HW BIS 1.6M+ADULT HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-35-060HF	CPAP HW BIS 1.6M+PAEDI/SMALL ADULT HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960E	Paediatric Embedded Single Limb Heated Wire Breathing System 1.6m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960EK	Paediatric Embedded Single Limb Heated Wire Breathing System 1.6m	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960HE	CPAP HW BIS 1.6M+PAED HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960HD	CPAP HW BIS 1.6M+INFANT HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960HC	CPAP HW BIS 1.6M+NEONATE HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-37-960HA	CPAP HW BIS 1.6M+PREMATURE HFNC+BV FILTER+PR VALVE	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-101	Paediatric Single Heated Wire Breathing System 1.6m Kit 1 with Pressure Port + 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-101U	Paediatric Single Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-201	Paediatric Dual Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-748	Paediatric Dual Heated Wire Breathing System 1.6m Cloverleaf Connector and Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-768	Paediatric 15mm 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
038-32-768U	Paed 15mm Single Heated Wire 1.6m B/S Water Trap AF Chamber with Filter Elbow	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-768H	Paed 15mm Single Heated Wire 1.6m B/S Water Trap AF Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-768H1	Paed 15mm Single Heated Wire 1.6m B/S Water Trap AF Chamber with Filter Elbow	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-32-768H2	Paediatric 15mm Single Heated Wire Breathing System 1.6m Water Trap Auto-Fill Chamber and Level Elbow	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N

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
038-01-162	Heated Wire 1.6m Limb With 22mm Adaptor MF	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
038-01-153	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
038-01-184	Adult Dual 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 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-252NS	Adult Ventimyst Dual Heated Wire Breathing System 1.6m Kit 1 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-253NS	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 with VeeFlo Small Kit 5 (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 VeeFlo Small Kit 5 (Non-Sterile)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-31-803NS	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
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
038-02-160B	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
038-02-161	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 + Ported Y-Piece + 1 x 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
038-33-101H	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 Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103H	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-103S	Neonatal Single Heated Wire Breathing System 1.6m S-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-101B	Neonatal Single Heated Wire Breathing System 1.6m B-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-102B	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
038-33-201S	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202S	Neonatal Dual Heated Wire Breathing System 1.6m S-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-201B	Neonatal Dual Heated Wire Breathing System 1.6m B-Type Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-202B	Neonatal Dual Heated Wire Breathing System 1.6m B-Type Kit 2	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-33-301	Neonatal Shielded Single Limb Heated Wire Breathing System 1.6m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-330U	Neonatal Circuit Single Limb Heated Wire Breathing System 1.5m Shielded (Tube) & AutoFill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340U	Neonatal Single Heated Wire Breathing System 1.25m with 1 x Water Trap	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340S	Neonatal Single Heated Wire Breathing System 1.25m with Water Trap including Extension Limb	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-341C	Neonatal Heated Wire Breathing System 1.25m Flying Lead with Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-342C	Neonatal 10mm Single Heated Wire 1.6m B/S Water Trap (BABYLOG)	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-346U	Neonatal Dual Heated Wire Breathing System 1.25m with Auto-Fill Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-350U	Neonatal Universal H/Wire B/System-Clover + Chamber	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340C	Neonatal Single Heated Wire Breathing System 1.6m Water Trap Auto-Fill Chamber Incubator Extension	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340C1	Neonatal Single Heated Wire Breathing System 1.25m Kit 1	Class Ila (Rule 2)	37706	Ventilator breathing circuit, single-use	N
038-03-340K	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
038-03-346C	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



435-305-015	Hygrovent S Bacterial Viral HMEF Small with Straight Catheter Mount 15F-22M/15M	Class Ila (Rule 2)	61134	Heatmoisture exchanger/microbial filter, sterile	N
HF55-F715	HF55 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
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
038-41-350/640	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
038-41-355/308-40	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
038-41-355/308-43	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
038-41-355/3091	ThermoShield Adult Bacterial Viral HMEF with Luer Port + Standard Catheter Mount	Class Ila (Rule 2)	46816	Heatmoisture exchanger/microbial filter, non-sterile	N
038-41-355/3091U	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
038-41-355/315U	ThermoShield HMEF Luer Port Flexi 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 Flexi 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
038-41-355/317-90	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
038-41-335L5	LuerSafe Adult Angled ThermoShield Bacterial Viral HMEF with Self-Sealing Luer Port	Class Ila (Rule 2)	46816	Heatmoisture exchanger/microbial filter, non-sterile	N
038-41-335L5U	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 and Elbow 22M/15F	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 and 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

391-100-000	Hygrovent Bacterial Viral HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/microbial filter, non-sterile	N
391-100-000U	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 S 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
356-006-000B	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
356-005-010B	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 S HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/microbial filter, non-sterile	N
362-200-000U	HME-Booster T-piece WFL + Hygrovent S HMEF	Class Ila (Rule 2)	46816	Heatmoisture exchanger/microbial filter, non-sterile	N

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PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
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
038-42-350E40	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 PNA	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
038-42-355301	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 22M15F	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 22M15F	Class Ila (Rule 2)	46816	Heat/moisture exchanger/ microbial filter, non-sterile	N
038-42-355311	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
038-42-355311U	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 22M15F	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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PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	GMDN CODE	GMDN TERM	ROHS APPLIES Y/N
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-22M15M	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 device 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
038-41-250P	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
038-11-260U	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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Product Code	Product Name	Classification	OMDN Code	OMDN Term	RHGS Applies Y/N
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					
038-41-2503TR	ThermoTrach Tracheostomy HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-2553TR	ThermoTrach Tracheostomy Low Resistance HME with Vent and Swivel Oxygen Port	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
038-41-2603TR	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

Product Code	Product Name	Classification	OMDN Code	OMDN Term	RHGS Applies Y/N
300-700-000 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
300-730-000U	Climatrach Tracheostomy HME with Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N
300-730-000 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 and Safety Valve	Class Ila (Rule 2)	35530	Heat/moisture exchanger, single-use	N



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Video Stylet (Sterile)
TF: 109a

Classic - Intermittent Urinary Catheters (Sterile)
TF: 117

Intended use: The ProVu Video Stylet (ProVu VS) is a sterile, single-use, video-enabled styler 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.

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 acquire 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	RHGS APPLIES Y/N
038-000-085	ProVu Single Use Video Styler with ET Tube Size 6.5	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-070	ProVu Single Use Video Styler with ET Tube Size 7.0	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-075	ProVu Single Use Video Styler with ET Tube Size 7.5	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y
038-000-080	ProVu Single Use Video Styler with ET Tube Size 8.0	Class Ila (Rule 5 & 12)	64758	Video-Intubation Endotracheal Tube	Y

PRODUCT CODE	PRODUCT DESCRIPTION	CLASSIFICATION UNDER ANNEX IX	OMDN CODE	OMDN TERM	RHGS 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					
UTAF08	WyCath Uncoated Intermittent Catheter Tapered Tip Female 18cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTAF10	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					
U4UP06	WyCath Uncoated Intermittent Catheter Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
H4UP06	WyCath Uncoated Intermittent Catheter Paediatric 25cm 05CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Paediatric - Soft Tip					
L4SP06	WyCath Uncoated Intermittent Catheter Soft Tip Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
U4SP10	WyCath Uncoated Intermittent Catheter Soft Tip Paediatric 30cm 10CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Paediatric - Thomann Tip					
UTP06	WyCath Uncoated Intermittent Catheter Thomann Tip Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
UTP08	WyCath Uncoated Intermittent Catheter Thomann Tip Paediatric 30cm 08CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N
WyCath Uncoated Intermittent Catheter Paediatric - Taper Tip					
UTAP06	WyCath Uncoated Intermittent Catheter Tapered Tip Paediatric 30cm 06CH	Class Ila (Rule 5)	45603	Single-administration urethral drainage catheter	N

Table with 5 columns: UTAP08, WyCam Uncoated Intermediate Catheter Tapered Tip Paediatric 30cm ØBC, Class I(a) (Rule 5), 45803, Single-administration urethral drainage catheter

Closed Suction Catheters (Sterile) TF: 119b

Intended use: Closed Suction Catheters are intended for endotracheal and tracheobronchial tree suctioning to remove secretions in ventilated patients fitted with an artificial airway.

Suction Catheters (Sterile) TF: 119a

Intended use: A flexible tube typically made of plastic designed for periodic aspiration of liquids and/or semi-solids from a patient's upper airway.

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N



Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N

Table with 6 columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N

Endotracheal (ET) Tubes (Sterile) TF: 123

Intended use: A hollow cylinder inserted orally or nasally into the trachea to provide an unobstructed airway to convey gases and vapours to and from the lungs during anaesthesia, resuscitation, and other situations where the patient is not properly ventilated.

EC Declaration of Conformity



Table with columns: Product Code, Description, Class, Rule, CE Mark, Description, Material, and CE Mark. Lists various oral and nasal tube products.

EC Declaration of Conformity



Table with columns: Product Code, Description, Class, Rule, CE Mark, Description, Material, and CE Mark. Lists various oral and nasal tube products.



EC Declaration of Conformity



Table with columns: Product Code, Description, Class, Rule, CE Mark, Description, Material, and CE Mark. Lists various reinforced and curved oral tubes.

EC Declaration of Conformity



Table with columns: Product Code, Description, Class, Rule, CE Mark, Description, Material, and CE Mark. Lists various reinforced and curved oral tubes.

EC Declaration of Conformity



EC Declaration of Conformity



Table with columns: Product ID, Description, Class, Rule, Model, Description, Class, Rule, Model, Description. Lists various Endotracheal Tubes and VentSeal HVLV Cuffed Oral/Nasal ET Tubes.



EC Declaration of Conformity



EC Declaration of Conformity



Table with columns: Product ID, Description, Class, Rule, Model, Description, Class, Rule, Model, Description. Lists VentSeal HVLV Cuffed Oral/Nasal ET Tubes and VentSeal Magill HVLV Cuffed Oral/Nasal ET Tubes.

EC Declaration of Conformity

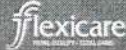


Table listing medical devices with columns for Product Code, Description, Classification, UDI, and Single Use status.

EC Declaration of Conformity



Table listing medical devices with columns for Product Code, Description, Classification, UDI, and Single Use status.

EC Declaration of Conformity



Table listing Endoscopic Bite Block devices with columns for Product Code, Description, Classification, UDI, and Single Use status.

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...

Table listing Endoscopic Bite Block devices with columns for Product Code, Description, Classification, UDI, and Single Use status.

EC Declaration of Conformity



Table listing DualGuard Adult Endoscopy Mouthpiece devices with columns for Product Code, Description, Classification, UDI, and Single Use status.



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.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Lists various suction yankauer models like 050-35-001, 050-35-002, etc.

Respiratory Humidifier (Non-Sterile)

TF: 132

Intended use: A mains electricity (AC-powered) device designed to heat and humidify air/room inspired by a patient to help maintain the mucous membranes of the respiratory tract typically during periods of prolonged respiratory support/therapy.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Lists various humidifier models like FL9000, FL9000EU, etc.



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.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Lists pocket resuscitation mask models like 010-909, 010-990U.

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 anesthetic gases to the upper airway. It is made of conductive or non-conductive rubber, polyvinyl chloride (PVC), or other sterilizable materials.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Lists various anaesthetic face mask models like 038-51-4003FL, 038-51-4003FLU, etc.

Table with columns: PRODUCT CODE, PRODUCT DESCRIPTION, CLASSIFICATION UNDER ANNEX IX, GMDN CODE, GMDN TERM, ROHS APPLIES Y/N. Lists various anaesthetic face mask models like 038-51-4105PPE, 038-52-4105FV, etc.






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

Final Audit Report

2023-07-26

Created:	2023-07-26
By:	elle morey-jones (elle.morey-jones@flexicare.com)
Status:	Signed
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"DOC-000003-Declaration of Conformity for Class IIa IIb Devices" History

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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	

