ECHIPAMED
P L U S
Moldova, MD - 2001, Chisinau, str. Valea Trandafirilor 24 "B", of. 2-7
tel. +373 (22) 234 349, 234 225; fax +373 (22) 234 225
e-mail: office@echipamed.com, info@echipamed.com

Nr. F/N
din 17.09.2023

Către Agenția Medicamentului
și Dispozitivelor Medicale

Notificare

pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

Solicitantul **„Echipamed-Plus" SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr	Nr. Cat.	Denumire	Denumire comercială	Model
1	MP01840	Catheter Mounts	ErgoStar	ErgoStar CM 40
2	MP01845	Catheter Mounts	ErgoStar	ErgoStar CM 45

Se anexează următoarele acte:

1. Declarații de conformitate CE.
2. Declarații de la producător privind desemnarea reprezentantului.
3. Declarație pe proprie răspundere.

Digitally signed by Iurchevici Valeriu
Date: 2023.09.17 15:50:03 EEST
Reason: MoldSign Signature
Location: Moldova

Data 17.09.2023 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	
Semnătura persoanei responsabile	

ECHIPAMED
P L U S
Moldova, MD - 2001, Chisinau, str. Valea Trandafirilor 24 “B”, of. 2-7
tel. +373 (22) 234 349, 234 225; fax +373 (22) 234 225
e-mail: office@echipamed.com, info@echipamed.com

Nr. F/N
din 17.09.2023

Către Agenția Medicamentului
și Dispozitivelor Medicale

Declarație pe proprie răspundere

Solicitant: **„Echipamed-Plus” SRL**, cu sediul str. Valea Trandafirilor 24B, of.80, MD-2001, mun. Chișinău, Republica Moldova, tel./fax: 022 23-42-25, e-mail: office@echipamed.com, declar pe proprie răspundere, cunoscînd prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificare dispozitivului medical:

Nr	Nr. Cat.	Denumire	Denumire comercială	Model
1	MP01840	Catheter Mounts	ErgoStar	ErgoStar CM 40
2	MP01845	Catheter Mounts	ErgoStar	ErgoStar CM 45

Sunt autentice și corespund realității.

Director Valeriu Iurchevici

Semnătura ________

Nr.	Numărul de catalog (referință)	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)	Modelul	Cod GMDN	Clasa dispozitivului
1	MP01840	Catheter Mounts	ErgoStar	ErgoStar CM 40	61346	IIa
2	MP01845	Catheter Mounts	ErgoStar	ErgoStar CM 45	61346	IIa

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

Manufacturer: **Drägerwerk AG & Co. KGaA**
Moislinger Allee 53-55
23542 Lübeck
GERMANY

SRN Manufacturer: DE-MF-000005329

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 010578 0039 Rev. 09

Report No.: 713253108_CN

Preceding Certificate No.: G10 010578 0039 Rev. 08

Valid from: 2023-03-14
Valid until: 2025-03-17

Date of Initial Issuance: 2020-03-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-03-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

Classification:	Class IIa
Device Group:	R02 - BREATHING CIRCUITS AND CATHETER MOUNTS R0301 - RESPIRATORY MASKS R030201 - VENTILATION BALLOONS R0401 - VENTILATION FILTERS R0402 - NATURAL BREATHING FILTERS Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS Z120309 - MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	A060304 - INTRA-OPERATION FLUID COLLECTION DEVICES
Intended Purpose:	-
Classification:	Class IIb
Device Group:	Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	Software intended to provide clinical information for the purpose of supporting patient management and the decision making process
Classification:	Class IIb
Device Group:	Z120804 - NEONATOLOGY INSTRUMENTS

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

Intended Purpose:	Warming therapy devices intended to provide controlled ambient conditions for premature babies and neonates in closed and open care therapy
Classification:	Class IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	Devices for the purpose of ventilation and/or anesthesia
Classification:	Class IIb
Device Group:	Z120309 - MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES
Intended Purpose:	Devices intended to distribute or supply gases, vacuum, electricity or data to equipment in diagnostic, therapy or surgery
Classification:	Class IIb
Device Group:	R020107 - THERMOREGULATED BREATHING CIRCUITS
Intended Purpose:	Inspiratory (and expiratory) heated disposable breathing circuit for conducting humidified breathing gas from humidifier to patient
Classification:	Class IIb
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	Devices intended to administer gases for the purpose of ventilation
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2020-03-18	713169482	-
01	2021-07-02	713184148	-
02	2021-09-30	713215188	-
03	2021-10-01	713215832	-
04	2021-10-04	713215842	-
05	2021-10-04	713219421	-
06	2021-11-22	713229134	-

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 09

07	2022-02-21	713213004	-
08	2022-10-06	713225304_CN	-
09	2023-03-14	713253108_CN	Supplemented: Device(s)/group of device(s) added

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Dräger

Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

To whom it may concern

Manufacturer's Authorization

May 25, 2023

We, Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck, Germany, who is an established and reputable manufacturer of medical equipment, having factories at Lübeck (Germany), Telford (United States), Andover (United States) and Shanghai (China), do hereby declare that

"Echipamed-Plus" SRL Valea Trandafirilor 24 "B", of. 2-7 MD-2001, Chisinau Republic of Moldova

is our official distributor and local representative for Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights of Drägerwerk AG & Co. KGaA in the territory of the Republic of Moldova.

We declare that only above mentioned Company is authorized to do registration, quote, seil, subsequently negotiate and sign contracts, as well as to perform installation and after sales Service of Anesthesia Devices, Incubators, Ventilation Machines, Monitoring, Pendant and Operating Lights manufactured by us in their own name and on their own account.

This authorization letter will remain valid until 31.12.2024.

Martin Koch
Managing Director Sub Region East Europe

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE135082211

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Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Dräger

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck
Germany

for the Scope of application

Design and development, production and distribution of diagnostic and therapeutic medical devices and installations as well as consulting and services in the field of medical technology

Revalstraße 1, 23560 Lübeck
Germany

for the Scope of application

Production and distribution of diagnostic and therapeutic medical devices and installations

has established and applies
a Quality Management System.

An audit was performed, Order No. **707037695**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-01-15** until **2024-01-14**.

Certificate Registration No.: **12 100 49423 TMS**.

Head of Certification Body
Munich, 2021-01-13

DAkkS Deutsche Akkreditierungsstelle D-ZM-16113-01-00

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstrasse 57 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010578 0031 Rev. 01

Holder of Certificate: **Drägerwerk AG & Co. KGaA**
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 010578 0031 Rev. 01

Report No.:	713193628
Valid from:	2021-01-18
Valid until:	2024-01-13

Date, 2021-01-18

Christoph Dicks
Head of Certification/Notified Body

«ECHIPAMED-PLUS» IDNO 1003600077677

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010578 0031 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices and Installations as well as Consulting and Services in the Field of Medical Technology. Diagnostic and Therapeutic Medical Devices and Installations: Anaesthetic Equipment, Infusion Equipment, Pediatric Equipment for Warming- and Photo-Therapy, Lung Ventilator Equipment, Monitoring Equipment, Clinical Decision Support Software, Patient Data Management Software, Equipment for Suction, Breathing-, Inhalation-, O2- and Aerosol-Therapy, Medical Gas Management and Supply Systems as well as Medical Lights

./.

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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010578 0037 Rev. 01

Manufacturer:

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
GERMANY

Facility(ies):

Drägerwerk AG & Co. KGaA
Revalstraße 1, 23560 Lübeck, GERMANY

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55, 23542 Lübeck, GERMANY

Product Category(ies):

**Anaesthetic equipment with standard accessories,
Infusion equipment with standard accessories,
Pediatric equipment with standard accessories,
Lung ventilator equipment with standard accessories,
Monitoring equipment with standard accessories,
Equipment for suction, breathing-, inhalation-, oxygen- and aerosol-therapy with standard accessories,
Medical supply units and terminal units for pressurized medical gases and vacuum,
Pipelines for compressed medical gases and vacuum,
Anaesthetic gas scaving systems, Components for medical gas management systems, Software for diagnosis based on clinical data incl. patient data, monitoring and device parameter, Visualization, diagnostic and therapeutic software for anesthesia and respiratory devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713162398

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2019-12-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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A4 / 07.17

Document Status	Released
Released Date	2022-12-02T12:03:13
Author(s) and Approval	Please see associated Document Release Reference: DR-00073321

en/de

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr. **MDR108-007-2212-029-0**
Date / Datum **2022-12-02**
Place / Ort **Germany - Lübeck**
Page / Seite **1 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Authorised representative / Europäischer Bevollmächtigter: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Single registration number (SRN)/ einmalige Registrierungsnummer: DE-MF-000005329

hereby declares under its sole responsibility that the / erklärt hiermit in alleiniger Verantwortung, dass

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
ErgoStar	Catheter Mounts	IIa	UMDNS 14-080/ GMDN 61346/ EMDN R0202

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

European regulation (EU) 2017/745 on medical devices. An examination of the quality management System has been carried out following Annex IX (Chapters I and III and section 4) of the regulation by the Notified Body:/

Verordnung (EU) 2017/745 über Medizinprodukte. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang IX (Kapitel I and III und Abschnitt 4) der Verordnung beschrieben, wurde durch die Benannte Stelle vorgenommen:
TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123

The quality management system also complies to EN ISO 9001 and EN ISO 13485./

Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.

This declaration is effective for products placed on the market as of the date of issue. Any modifications of the device not authorized by Dräger will invalidate this declaration./
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Produkt führt zur Ungültigkeit dieser Erklärung.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
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Postal address:
23542 Lübeck, Germany
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Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR108-007-2212-029-0**
Date / Datum	**2022-12-02**
Place / Ort	**Germany - Lübeck**
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For the signature on behalf of Dräger see upper left corner of page 1./
Für die Unterschrift im Namen von Dräger siehe linke obere Ecke der Seite 1.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
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IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk
Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for
Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

EU Declaration of Conformity
EU-Konformitätserklärung

CE 0123

Document No. / Dokument Nr.	**MDR108-007-2212-029-0**
Date / Datum	**2022-12-02**
Place / Ort	**Germany - Lübeck**
Page / Seite	**3 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
ErgoStar	Catheter Mounts
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+A1:2020 *(IEC 62366-1: 2015 COR 1 2016 AMD1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 *(IEC 60601-1-6: 2010 AMD 1 2013 A2:2020)*	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
EN ISO 18562-1:2020 *(ISO 18562-1:2017)*	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
EN ISO 10993-1:2020 *(ISO 10993-1:2018)*	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment

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EU Declaration of Conformity
EU-Konformitätserklärung

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EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 5367:2014 *(ISO 5367:2014)*	Anaesthetic and respiratory equipment - Breathing sets and connectors
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

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EU Declaration of Conformity
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
MP01840	ErgoStar CM 40	0404867512080076K19Z000ST
MP01845	ErgoStar CM 45	0404867512080076K19Z000ST
MP01850	ErgoStar CM 50	0404867512080076K19Z000ST
MP01855	ErgoStar CM 55	0404867512080076K19T010RL
MP01860	ErgoStar CM 60	0404867512080076K19Z000ST
MP01890	ErgoStar AC 90	0404867512080076K19T020RP
MP01895	ErgoStar AC 95	0404867512080076K19T020RP

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Localitatea	**Germany - Lübeck**
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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reprezentant autorizat: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Număr unic de înregistrare (SRN): DE-MF-000005329

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
ErgoStar	Catheter Mounts	IIa	UMDNS 14-080/ GMDN 61346/ EMDN R0202

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.

Această declaraţie are efect pentru produsele puse pe piaţă începând cu data emiterii. Orice modificare a dispozitivului neautorizată de Dräger va anula această declaraţie.

Aceasta este o traducere a documentului original (en/de) şi din această cauză nu necesită o semnătură.

Director
Quality & Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Timo Harms

Director
Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

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Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
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Commercial register:
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General partner: Drägerwerk Verwaltungs AG
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Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
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Anton Schrofner

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Declaraţie de conformitate UE

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Numele produsului	**Categoria dispozitivului**
ErgoStar	Catheter Mounts
Standarde aplicate în totalitate sau parţial:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+A1:2020 *(IEC 62366-1: 2015 COR 1 2016 AMD1:2020)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6: 2010+A1:2015+A2:2021 *(IEC 60601-1-6: 2010 AMD 1 2013 A2:2020)*	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
EN ISO 18562-1:2020 *(ISO 18562-1:2017)*	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
EN ISO 10993-1:2020 *(ISO 10993-1:2018)*	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets

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EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 5367:2014 *(ISO 5367:2014)*	Anaesthetic and respiratory equipment - Breathing sets and connectors
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

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Declaraţie de conformitate UE

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MP01840	ErgoStar CM 40	0404867512080076K19Z000ST
MP01845	ErgoStar CM 45	0404867512080076K19Z000ST
MP01850	ErgoStar CM 50	0404867512080076K19Z000ST
MP01855	ErgoStar CM 55	0404867512080076K19T010RL
MP01860	ErgoStar CM 60	0404867512080076K19Z000ST
MP01890	ErgoStar AC 90	0404867512080076K19T020RP
MP01895	ErgoStar AC 95	0404867512080076K19T020RP

Document Status	Released
Released Date	2023-02-22T23:52:53
Author(s) and Approval	Please see associated Document Release Reference: DR-00078043

en/de

EU Declaration of Conformity
EU-Konformitätserklärung

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Authorised representative / Europäischer Bevollmächtigter: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Single registration number (SRN)/ einmalige Registrierungsnummer: DE-MF-000005329

hereby declares under its sole responsibility that the / erklärt hiermit in alleiniger Verantwortung, dass

Product Name / Produktbezeichnung	Device Category / Produktkategorie	Device Class / Geräteklasse	UMDNS Code / GMDN Code / EMDN Code
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

meets the following provisions:
mit den folgenden Bestimmungen übereinstimmt:

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European regulation (EU) 2017/745 on medical devices. An examination of the quality management System has been carried out following Annex IX (Chapters I and III and section 4) of the regulation by the Notified Body:/

Verordnung (EU) 2017/745 über Medizinprodukte. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang IX (Kapitel I and III und Abschnitt 4) der Verordnung beschrieben, wurde durch die Benannte Stelle vorgenommen:
TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123

The quality management system also complies to EN ISO 9001 and EN ISO 13485./

Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.

This declaration is effective for products placed on the market as of the date of issue. Any modifications of the device not authorized by Dräger will invalidate this declaration./
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Produkt führt zur Ungültigkeit dieser Erklärung.

For the signature on behalf of Dräger see upper left corner of page 1./
Für die Unterschrift im Namen von Dräger siehe linke obere Ecke der Seite 1.

Head of Regulatory Affairs
Business Unit Hospital Consumables & Accessories
Medical Division

Holger Wagner

Director Research & Development
Business Unit Hospital Consumables & Accessories
Medical Division

Kalle Heckmann

Drägerwerk AG & Co. KGaA
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IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board for Drägerwerk AG & Co. KGaA and Drägerwerk Verwaltungs AG:
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Executive Board:
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Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Product Name / Produktbezeichnung	**Device Category / Produktkategorie**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Applied Standards in full or in part / Vollständig oder teilweise angewendete Normen:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971:2019 *(ISO 14971 :2019)*	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021 *(ISO 15223-1:2021)*	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.
EN ISO 80601-2-12:2020 *(ISO 80601-2-12:2020)*	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management Process
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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EU Declaration of Conformity
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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
EN ISO 80369-1:2018 *(ISO 80369-1:2018)*	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Extend of conformity assessment / Umfang der Konformitätsbewertung		
Part Number / Sachnummer	Product Name / Produktbezeichnung	Basic UDI-DI
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF

Declaraţie de conformitate UE

CE 0123

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Pagina	**1 / 5**

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Reprezentant autorizat: N/A

EC Certificate: G10 010578 0039
Valid until: 2025-03-17

Număr unic de înregistrare (SRN): DE-MF-000005329

declară prin prezenta pe proprie răspundere că

Numele produsului	Categoria dispozitivului	Clasa dispozitivului	Codul UMDNS / Codul GMDN / Codul EMDN
Filter CareStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter SafeStar Plus	Microbial medical gas filter, single use	IIa	UMDNS 14-352/ GMDN 60837/ EMDN R040101
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter	IIa	UMDNS 11-710/ GMDN 46816/ EMDN R040102
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040102
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use	IIa	UMDNS 15-645/ GMDN 35530/ EMDN R040201

îndeplinește următoarele cerințe:

REGULAMENTUL (UE) 2017/745 privind dispozitivele medicale. O analiză a sistemului de management al calităţii a fost efectuată conform Anexei IX (capitolele I şi III şi secţiunea 4) a reglementării Organismului notificat: **TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, NB 0123**
Sistemul de management al calităţii îndeplineşte de asemenea cerinţele standardelor EN ISO 9001 şi EN ISO 13485.

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Declaraţie de conformitate UE

Nr. document	**MDR108-043-2302-003-0**
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Pagina	**2 / 5**

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Head of Regulatory Affairs Business Unit Hospital Consumables & Accessories Medical Division	Director Research & Development Business Unit Hospital Consumables & Accessories Medical Division
Holger Wagner	Kalle Heckmann

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Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Numele produsului	**Categoria dispozitivului**
Filter CareStar Plus	Microbial medical gas filter, single use
Filter SafeStar Plus	Microbial medical gas filter, single use
Filter/HME TwinStar Plus	Heat/moisture exchanger/ microbial medical gas filter
HME HumidStar Plus	Humidifier, heat/moisture exchange, single-use
HME HumidStar Trach Plus	Humidifier, heat/moisture exchange, single-use
Standarde aplicate în totalitate sau parţial:	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical electrical equipment – Part 1 General requirements for basic safety and essential performance
EN 62366-1:2015+AC:2015+ AC:2016 *(IEC 62366-1:2015 COR 1 2016)*	Medical devices - Part 1: Application of usability engineering to medical devices
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EN ISO 20417:2021 *(ISO 20417:2021)*	Medical devices - Information to be supplied by the manufacturer
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EN ISO 80601-2-13:2012+A2:2019 *(ISO 80601-2-13:2011+AMD1:2015 +AMD2:2018)*	Medical Electrical Equipment – Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation
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ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

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ISO 18190:2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
EN ISO 5356-1:2015 *(ISO 5356-1:2015)*	Anaesthetic and respiratory equipment; Conical connectors – Part 1: Cones and sockets
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EN ISO 23328-1:2008 *(ISO 23328-1:2003)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 1: Salt Test Method to assess Filtration Performance
EN ISO 23328-2:2009 *(ISO 23328-2:2002)*	Breathing system Filters for anaesthesia and Respiratory Use - Part 2: Non-Filtration Aspects
EN ISO 9360-1:2009 *(ISO 9360-1:2000)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 1: HMES for use with Minimum Tidal Volumes of 250 ml
EN ISO 9360-2:2009 *(ISO 9360-2:2001)*	Anaesthetic and Respiratory Equipment - heat and Moisture Exchangers (HMES) for humidifying respired Gases in Humans - Part 2: HMES for use with Tracheostomized Patients having Minimum Tidal Volumes of 250 ml
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

CE 0123

Declaraţie de conformitate UE

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Evaluarea extinsă a conformităţii		
Cod articol	Numele produsului	UDI-DI de bază
MP05755	Filter CareStar 35 Plus	0404867512080436K19S030SB
MP05770	Filter CareStar 20 Plus	0404867512080436K19S030SB
MP05785	Filter SafeStar 90 Plus	0404867512080436K19S040SE
MP05790	Filter SafeStar 55 Plus	0404867512080436K19S040SE
MP05795	Filter SafeStar 60A Plus	0404867512080436K19S040SE
MP05800	Filter/HME TwinStar 90 Plus	0404867512080436K19S050SH
MP05801	Filter/HME TwinStar HEPA Plus	0404867512080436K19S060SL
MP05805	Filter/HME TwinStar 55 Plus	0404867512080436K19S050SH
MP05810	Filter/HME TwinStar 60A Plus	0404867512080436K19S050SH
MP05815	Filter/HME TwinStar 25 Plus	0404867512080436K19S050SH
MP05820	Filter/HME TwinStar 9 Plus	0404867512080436K19S050SH
MP05730	HME HumidStar 55 Plus	0404867512080436K19Z000TK
MP05735	HME HumidStar 25 Plus	0404867512080436K19Z000TK
MP05845	HME HumidStar 2 Plus	0404867512080436K19T010SC
MP05750	HME HumidStar Trach Plus	0404867512080436K19T020SF