CE 0123	**EC Declaration of Conformity** *EG Konformitätserklärung*	Date / *Datum* 2020-05-26
	European Directive 93/42/EEC, Annex II *Europäische Richtlinie 93/42/EWG, Anhang II*	Document ID / *Dokument Nr.* MD101-012-2005-008-0

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

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

Product Name / *Produktbezeichnung*	Medical Device / *Medizinprodukt*	Device Class	UMDNS Code / GMDN Code
Drägersorb 800 Plus	CO_2 Absorber	IIa	17-509 / 42414
Drägersorb Free	CO_2 Absorber	IIa	17-509 / 42414
CLIC Absorber 800 Plus	CO_2 Absorber	IIa	17-509 / 42414
CLIC Absorber Free	CO_2 Absorber	IIa	17-509 / 42414
Infinity ID CLIC Absorber 800 Plus	CO_2 Absorber	IIa	17-509 / 42414
Infinity ID CLIC Absorber Free	CO_2 Absorber	IIa	17-509 / 42414

meets the provisions of the European Directive 93/42/EEC on medical devices. An examination of the quality management system has been carried out following Annex II.3 of the directive by the Notified Body TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany, EC No. 0123. The quality management system also complies to EN ISO 9001 and EN ISO 13485.
This declaration is effective for products placed on the market as of the date of issue. Any modifications of the medical device not authorized by Dräger will invalidate this declaration.

mit den Bestimmungen der europäischen Richtlinie 93/42/EWG (Medizinprodukte) übereinstimmt. Eine Überprüfung des Qualitätsmanagementsystems, nach den Regeln wie in Anhang II.3 der Richtlinie beschrieben, wurde durch die Benannte Stelle TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 München, EU Kennnummer 0123, vorgenommen. Das Qualitätsmanagementsystem erfüllt weiterhin die Anforderungen gemäß EN ISO 9001 und EN ISO 13485.
Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Dräger autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung.

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 Dräger Regulatory Affairs D-23542 Lübeck

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

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600071677

Dräger

CE 0123	**Appendix I to EC Declaration of Conformity** *Anlage zur I zur EG Konformitätserklärung*	Date / *Datum* 2020-05-26
	European Directive 93/42/EEC *Europäische Richtlinie 93/42/EWG*	Document ID / *Dokument Nr.* MD101-012-2005-008-0-00

Drägerwerk AG & Co. KGaA
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23542 Lübeck
Germany

Product name / *Produktbezeichnung*	Medical device / *Medizinprodukt*
Drägersorb 800 Plus	CO_2 Absorber
Drägersorb Free	CO_2 Absorber
CLIC Absorber 800 Plus	CO_2 Absorber
CLIC Absorber Free	CO_2 Absorber
Infinity ID CLIC Absorber 800 Plus	CO_2 Absorber
Infinity ID CLIC Absorber Free	CO_2 Absorber

Applied Standards in full or in part / *Vollständig oder teilweise angewendete Normen:*

EN ISO 10993-1:2009 AC 2010 *(ISO 10993-1:2009 COR 2010)*	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 14971:2012 *(ISO 14971:2007 + Cor:2007)*	Medical Devices - Application of Risk Management to Medical Devices
EN 62366:2015 AC 2015 *(IEC 62366:2015 Cor:2016)*	Medical devices - Application of usability engineering to medical devices
EN ISO 8835-2: 2009 *(ISO 8835-2: 2007)*	Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems
EN ISO 80601-2-13: 2012 *(ISO 80601-2-13: 2011)*	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
EN ISO 17664:2017 *(ISO 17664:2017)*	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
USP 36 NF 31: 2013	United States Pharmacopeia 36 - National Formulary 31

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

Timo Harms

Dräger Werk AG & Co. KGaA
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REPUBLICA MOLDOVA mun. CHIȘINĂU SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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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
Anton Schrofner
Dr. Reiner Piske

CE 0123	**Appendix II to EC Declaration of Conformity** *Anlage II zur EG Konformitätserklärung*	Date / *Datum* 2020-05-26
	European Directive 93/42/EEC *Europäische Richtlinie 93/42/EWG*	Document ID / *Dokument Nr.* MD101-012-2005-008-0-ECA

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

Extent of conformity assessment / Umfang der Konformitätsbewertung	
Part No. / ***Sach Nr.***	**Product name /** ***Produktbezeichnung***
MX00001	Drägersorb 800 plus (5 L)
MX00004	CLIC Absorber 800+
MX00013	Intermediate plate
MX50004	Infinity ID CLIC absorber 800+
MX50050	Drägersorb Free (5 L)
MX50090	CLIC adapter
MX50100	CLIC absorber Free
MX50120	Infinity ID CLIC absorber Free

Director
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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

CE 0123	***Change log to EC Declaration of Conformity*** *Änderungsverlauf zur EG-Konformitätserklärung*	Date / *Datum* 2022-07-05
	European Directive 93/42/EEC **European Directive 2011/65/EU** *Europäische Richtlinie 93/42/EWG* *Europäische Richtlinie 2011/65/EU*	Document ID / *Dokument Nr.* MD101-012-2005-008-0-00B

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

The below listed changes resulting in an update of the EC Declaration of Conformity of the Drägersorb are considered non-significant changes in design or intended purpose according to article 120 EU 2017/745. The last issued EC Declaration of Conformity remains valid.

Change log to EC Declaration of Conformity / *Änderungsverlauf der EG-Konformitätserklärung*
for modifications to Drägersorb that are considered non-significant changes in design or intended purpose.
für Änderungen an Drägersorb, die als nicht signifikante Änderungen in Bezug auf Design oder Zweckbestimmung angesehen werden.

Change No. / *Änderungs-Nr.*	Date / *Datum*	Remark / *Anmerkung*
--	2020-05-26	Last declaration of Conformity issued under Council directive 93/42/EEC on medical devices
A	2021-07-08	Implementation of new plant for filling of Drägersorb Clic due to higher demand; for the efficiency of the plant a new carton design is needed.
B	2022-07-05	Introduction of alternative brand of PPSU for the adapter MX50090

Signature

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

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ECHIPAMED-PLUS SRL
IDNO 1003600071677

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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. 13

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, Certification, Validation and Verification Regulations 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. 13

Report No.:	713334366
Preceding Certificate No.:	G10 010578 0039 Rev. 12
Valid from:	2024-09-20
Valid until:	2025-03-17
Date of Initial Issuance:	2020-03-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-20

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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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. 13

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
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

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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. 13

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
Classification:	Class IIb
Device Group:	Z120401 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS
Intended Purpose:	Devices intended to provide clinical data on the network to support diagnosis and therapy decisions
Classification:	Class IIb
Device Group:	Z1203019092 - VARIOUS INSTRUMENTS FOR ANAESTHESIA AND PULMONARY VENTILATION SUPPORT - MEDICAL DEVICE SOFTWARE
Intended Purpose:	Software intended to support the decision making process in anesthesia and/or intensive care
Classification:	Class IIa
Device Group:	Z121590 - VARIOUS PNEUMOLOGY AND RESPIRATORY PHYSIOPATHOLOGY INSTRUMENTS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z120390 - VARIOUS INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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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. 13

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	-
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
10	2024-01-09	713298423	Supplemented: Device(s)/group of device(s) added
11	2024-02-12	713298535	Supplemented: Device(s)/group of device(s) added
12	2024-04-26	713312303	Supplemented: Device(s)/group of device(s) added
13	2024-09-20	713334366	Supplemented: Device(s)/group of device(s) added

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