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

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. 14

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. 14

Report No.:	713336654
Preceding Certificate No.:	G10 010578 0039 Rev. 13
Valid from:	2025-03-18
Valid until:	2030-03-17
Date of Initial Issuance:	2020-03-18

Issue date: 2025-02-03

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Iurchevici Valeriu
Date: 2026.03.26 16:21:32 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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(Class IIa and Class IIb Devices)

No. G10 010578 0039 Rev. 14

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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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. 14

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. 14

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
14	2025-03-18	713336654	Renewal of certificate

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

F/N din 27.03.2026

Către Grupul de lucru al
IMSP SCMC „V. Ignatenco”

DECLARAȚIE

Prin prezenta compania „**ECHIPAMED-PLUS” SRL**, în conformitate cu condiţiile expuse în documentele aferente invitaţiei de participare la Licitaţia nr. **21582870 / ocds-b3wdp1-MD-1773817324696** din **27.03.2026** cu privire la achiziționarea **“Necesarul de piese de schimb, accesorii și consumabile pentru dispozitive medicale pentru anul 2026",** cu respect Vă comunicăm, că în conformitate cu standardele de serviciu ale companiei germane Dragerwerk AG & Co. KGaA, informațiile despre piesele de schimb și seturile de mentenanță nu se află și nu sunt reflectate în cataloage/broșuri separate sau documentație tehnică de acces public liber.

Respectuos amintim, că în calitate de unic distribuitor oficial în Republica Moldova pentru tot spectrul de producție medicală (inclusiv dispozitive propriu-zise, soluții arhitecturale, accesorii, consumabile, piese de schimb, reparații și mentenanță) al companiei germane Dragerwerk AG & Co. KgaA, dispunând de centru tehnic propriu cu ingineri certificați (actele confirmative se anexează), compania „ECHIPAMED-PLUS” SRL operează doar cu produse originale Draeger, de producție proprie sau terță, acceptată oficial de producător.

Cu stimă,

Director
“ECHIPAMED-PLUS” SRL
Iurchevici Valeriu

Certificate No.
NC-1803

CERTIFICATE

Issued for:

HYDROLAB
WATER PURIFICATION SYSTEMS

HYDROLAB Sp. z o.o.

ul. Wesoła 1
83-010 Straszyn

Management Systems Certification Bureau of Polski Rejestr Statków S.A., al. gen. Józefa Hallera 126, 80-416 Gdańsk, certifies that the Quality Management System of the above Organization has been assessed and found to be in accordance with the requirements of:

ISO 9001:2015

Scope of certification:

DESIGN, MANUFACTURE, SERVICE AND TECHNICAL CONSULTANCY IN THE FIELDS OF WATER TREATMENT SYSTEMS FOR LABORATORY AND INDUSTRIAL PURPOSES

Certificate first issue: **05.02.2009**

The Certificate is valid until: **01.02.2027**

Gdańsk, 02.02.2024

PCA
Polskie Centrum Akredytacji
Certyfikacja Systemów Zarządzania
AC 014

Member of Multilateral Recognition Arrangement IAF

Certification Division Director
Dariusz Denis

CHIPAMED-PLUS
IDNO 1003600077677

www.prs.pl

HYDROLAB

HYDROLAB SP. Z O.O. SP.K.
Wesola 1 str.
83-010 Straszyn
POLAND

phone.: +48 58 341 16 69
+48 58 341 90 00
fax: +48 58 585 86 97

biuro@hydrolab.pl
www.hydrolab.eu

CONFORMITY DECLARATION CE

With a full responsibility, we declare that products:

water purification systems (demineralizers) – models: ***TECHNICAL 5 PLUS, TECHNICAL 5/C PLUS, TECHNICAL 10 PLUS, TECHNICAL 10/C PLUS, TECHNICAL 20 PLUS, TECHNICAL 20/C PLUS, TECHNICAL 30 PLUS, TECHNICAL 30/C PLUS, TECHNICAL 40 PLUS, TECHNICAL 60 PLUS***

fit the requirements of directives listed below:

- low-voltage electric device (LVD) No 2014/35/EU

- electromagnetic compatibility (EMC) No 2014/30/EU

- on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) 2011/65 / EU

Evaluation was performed by using harmonized standards:

• PN-EN 61010 Wymagania bezpieczeństwa dotyczące elektrycznych przyrządów do pomiarów, sterowania i użytku z laboratoriach.
• PN-EN 61326 Wyposażenie elektryczne do pomiarów, sterowania i użytku w laboratoriach. Wymagania dotyczące kompatybilności elektromagnetycznej (EMC),
• PN-EN 62311 Ocena sprzętu elektronicznego i elektrycznego związana z ograniczeniami narażania ludzi na działanie pól elektromagnetycznych (0 Hz - 300 GHz)
• PN-EN 50581 Dokumentacja techniczna oceny wyrobów elektrycznych i elektronicznych z uwzględnieniem ograniczenia stosowania substancji niebezpiecznych

Last two digits of the year, when the CE was issued: 14.

Date: 02/01/2021

Przemysław Ganczarek

HYDROLAB Sp. z o.o. Sp.K. ul. Wesoła 1, 83-010 Straszyn

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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 18 04 92076 008

Manufacturer:
Masimo Corporation
52 Discovery
Irvine CA 92618
USA

EC-Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies):
Pulse Oximeters and Accessories (Cables and Sensors). Telemetric Physiologic Monitoring System, Respiratory Monitors and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Regional Oximeters and Accessories (Cables and Sensors), Physiologic Monitoring Systems (for Blood Pressure and Body Temperature), Capnography Monitors and Accessories (Sampling Lines and Cannulas)

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.: 72137695

Valid from: 2018-07-16
Valid until: 2023-07-15

0405276739383 9

Date, 2018-07-06

Stefan Preiß

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

A1 / 04.11

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TÜV SÜD 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 18 04 92076 008

Facility(ies):

Masimo Corporation
52 Discovery, Irvine CA 92618, USA

Masimo Corporation
40 Parker, Irvine CA 92618, USA

Masimo Corporation
9600 Jeronimo, Irvine CA 92618, USA

Industrial Vallera de Mexicali, S.A de C.V
Calzada del Oro # 2001, 21600 Parque Ind. Palaco Mexicali BC, MEXICO

Masimo Corporation
15776 Laguna Canyon Road, Irvine CA 92618, USA

Industrial Vallera de Mexicali S.A. de C.V.
Calle José López Portillo, 104-A, Parque Industrial, Código Postal, 83455 San Luis Rio Colorado, Sonora, MEXICO

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A1 / 04.11

Masimo
52 Discovery
Irvine, CA 92618

June 19, 2023

Re: Masimo's Declaration Confirming Conditions for EU MDR Extension per Regulation 2023/607 are Fulfilled

To whom it may concern:

Masimo declares its legacy devices are covered by the transitional period stated in Regulation (EU) 2023/607, amending Regulations (EU) 2017/745. Masimo's certificate is issued by TÜV SÜD in accordance with Council Directives 93/42/EEC, was still valid on 26 May 2021, and has not been withdrawn afterwards. Masimo's EC Certificate remains valid after the expiry date of the certificate until December 31, 2028 set by EU MDR Amendment 2023/607. Masimo has fulfilled all conditions required to continue to place medical devices in the market.

Legal Manufacturer:
Masimo Corporation
52 Discovery, Irvine, CA, 92618, United States of America
SRN: US-MF-000010641

European Authorized Representative (EAR):
Medical Device Safety Services (MDSS)
Schiffgraben 41, 30175 Hannover, Germany
SRN: DE-AR-000005430

Notified Body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany
NB ID: 0123

Certificate Number: G1 092076 0024
End Date of Transitional Period: 31 December 2028

Device Classification: IIa, IIb
Devices Covered by Extension: Pulse Oximeters and Accessories (Cables and Sensors), Telemetric Physiologic Monitoring System, Respiratory Monitors and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Regional Oximeters and Accessories (Cables and Sensors), Physiologic Monitoring Systems (for Blood Pressure and Body Temperature), Capnography Monitors and Accessories (Sampling Lines and Cannulas), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System.

Conditions laid down in Article 120(3c) as amended by regulation 2023/607.

a. Masimo medical devices continue to comply with Council Directive 93/42/EEC;
b. There are no significant changes in the design and intended purpose of Masimo's medical devices;
c. Masimo medical devices do 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;
d. Masimo Corporation has put in place a quality management system in accordance with Article 10(9);
e. Masimo has lodged a formal application with TÜV SÜD covering all Masimo medical devices. Masimo and TÜV SÜD have signed a written agreement in accordance with Regulation 2023/607.

Sincerely,

Mathew Jimenez
Senior Vice President, Worldwide Quality & Compliance
Email: mjimenez@masimo.com
Phone: +1 949-297-7558