Dräger

Technology for Life

Digitally signed by Iurchevici Valeriu
Date: 2025.02.28 13:43:03 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

Our reference
739/22 // ew-de

Phone
+49 451 882-2471

E-mail
Erika.Wagner@draeger.com

To whom it may concern

November 11, 2024

Manufacturer's Authorization

We, Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck, Germany, an established and reputable manufacturer of medical equipment, with manufacturing facilities located in Germany, Moislinger Allee 53-55, 23558 Lübeck, Germany and in the United States of America through Draeger Medical Systems, Inc, 3135 Quarry Road, Telford, PA 18969, USA, and 6 Tech Drive, Andover, MA 01810, USA, and in China through Shanghai Dräger Medical Instrument Co. Ltd., Building 3, No. 229 Hu Po Rd, Shanghai International Medical Zone, Pudong District, Shanghai, China, 201321, do hereby declare that

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

is our 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, sell, 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 31.12.2025.

Drägerwerk AG & Co. KGaA

Fiesser Caroline — Digital unterschrieben von Fiesser Caroline, Datum: 2024.11.11 17:17:54 +01'00'

ppa. T. Engel — Digitally signed by Tatjana Engel, Date: 2024.11.12 12:42:04 +01'00'

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

Dr. Caroline Fiesser
Authorized Representative

Tatjana Engel
Authorized Representative

"ECHIPAMED-PLUS" SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, CHISINAU, IDNO 1003600077677

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. 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
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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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MASIMO INTERNATIONAL SARL
Puits-Godet 10
2000 Neuchâtel - SWITZERLAND

LETTER OF AUTHORIZATION

September 13th , 2013

Dear Sir/Madam,

Masimo International SARL (**"Masimo"**), as the owner and producer of the products listed below, with its corporate headquarters at Puits-Godet 10, 2000, Neuchatel, Switzerland, hereby appoints **"Echipamed Plus SRL"** a company organized and existing under the laws of Republic of Moldova and with its business address at Str. Valea Trandafilirol 24 B, of 80, Chisinau, 2001, Republic of Moldova (**"Echipamed Plus SRL"**), as an authorized distributor in the territory of Republic of Moldova on Masimo's behalf.

This appointment applies to the following products with all related accessories and attachments:

- LNOP® Sensors (Adhesive & Reusable) and Patient Cables Product Family
- LNOPv® Adhesive Sensor product family
- LNOP® MAC-1 Cables
- LNOP® Red Patient cables product family
- LNOP® Adapter Cables
- LNCS®Sensors (Adhesive & Reusable) and Patient Cables Product Family
- LNC™ Patient Cables (for use with Masimo SET Devices)
- LNCS® Adapter Cables
- LNCS® MAC cables
- M-LNCS™ Sensors (Adhesive, Specialty & Reusable) and Patient Cables Product Family
- Red Sensors
- Red™ Direct Connect Sensors (for use with Masimo Rainbow SET Devices)
- Direct Connect Sensors (for use with Masimo SET Devices)
- Rainbow® Sensors (Adhesive, Reusable and Disposable) and Patient Cables, Product family
- Rainbow® Direct Connect Sensors
- Masimo Sensor Accessories
- Masimo Sensor Sample pacs
- SpO2.com Sensors & cables product family,
- Masimo SET® Pulse Oximetry Devices (monitors)
- Masimo Rainbow SET™ Devices (monitors)
- Masimo SET Pulse Oximeters & Pulse CO-Oximeters and their accessories
- Handheld Pulse Oximeters & their accessories

PHONE: +41 (0)32 720 11 11 FAX: +41 (0)32 724 14 48 WWW.MASIMO.COM

MASIMO INTERNATIONAL SÀRL
Puits-Godet 10
2000 Neuchâtel - SWITZERLAND

- Masimo Rainbow SET™ Device Options (including the following Rainbow Application Parameters):

  Total Hemoglobin (SpHb)
  Carboxyhemoglobin (SpCO)
  Methemoglobin (SpMet)
  PI Delta 3D Alarm
  DESAT index 3D Alarm
  Pleth Variability Index (PVI)

- SatShare® Cables
- PSN (Patient Safety Net)
- OEMs Monitor Upgrades and Compatible Devices

Echipamed Plus SRL is authorised to import, market, sell, commision and service the products and to participate in public and private tenders. This appointment is valid from the date first written above and terminates automatically if the Distribution Agreement ends for any reason.

Yours Sincerely,

George Burridge
Director, Finance
Masimo International

Masimo
52 Discovery
Irvine CA 92618

EC DECLARATION OF CONFORMITY

Manufacturer's Name:	**Masimo Corporation**
Business Address:	**52 Discovery, Irvine, CA 92618, USA**
European Representative:	**Medical Device Safety Service GmbH** **Schiffgraben 41, 30175 Hannover, Germany**
Product(s):	**RAS Sensors** **DC rainbow SET Reusable Sensors** **DC SET Reusable Sensors** **LNCS SET Disposable Sensors** **LNCS SET Reusable Sensors** **M-LNCS rainbow SET Disposable Sensors** **M-LNCS rainbow SET Reusable Sensors** **M-LNCS SET Disposable Sensors** **M-LNCS SET Reusable Sensors** **Rad-G Reusable Sensors** **RD rainbow SET Disposable Sensors** **RD rainbow SET Reusable Sensors** **RD SET Disposable Sensors** **RD SET Reusable Sensors** **Red SET Reusable Sensors** **SpO2.COM Sensors** ***(see Attachment for detailed product names)***
Classification:	**Class IIb (per MDD Annex IX, Rule 10)**
Conformity Assessment Route:	**MDD Annex II (excluding section 4)**
UMDNS and GMDN Code(s):	***(see Attachment for codes and terms)***
Standards Applied:	**Refer to Essential Requirements Checklist in TFA-1186, Harmonized Standards Applied in support of MDD and RoHS**

We, Masimo Corporation, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of European Directive 93/42/EEC on Medical Devices (MDD), as amended, as well as of European Directive 2011/65/EU on Restriction of Hazardous Substances (RoHS). All supporting documentation is retained under the premises of the manufacturer.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2016.

Notified Body:	**TÜV SUD Product Services GmbH** **Ridlerstrasse 65, 80339 Munchen-Germany** **Identification no. 0123**
EC-Certificate:	**G1 092076 0024 Rev. 00**

Signature:

Linus Park
VP, Regulatory
Masimo Corporation

2022-05-24
Date

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

Masimo
52 Discovery
Irvine CA 92618

ATTACHMENT

Product Family	Product Name	Part Number	UMDNS Code	GMDN Code
RAS Sensors	RAS-125c	3456	13754 Stethoscopes, Electronic	13754 Electronic stethoscope
	RAS-125c	3475		
	RAS-125c	3401		
	RAS-125c	3483		
	RAS-45	4171		
	RAS-45 Inf/Neo	4425		
	Radius VSM RAS-45	4828		
DC rainbow SET Reusable Sensors	rainbow DCI-dc3	2201	17594 Probes, Oximeter	47582 Pulse Co-oximeter probe, reusable
	rainbow DCI-dc12	2202		
	rainbow DC-3 SC 200	2646		
	rainbow DCI-dc8	2407		
DC SET Reusable Sensors	DCSC	1396	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	DC-8	2387		
	DBI-dc3	2651		
	DBI-dc8	2652		
LNCS SET Disposable Sensors	LNCS Adtx	1859	17594 Probes, Oximeter	31658 Pulse oximeter probe, single-use
	LNCS Neo-L	1862		
	LNCS Pdtx	1860		
	LNCS Inf-L	1861		
	LNCS NeoPt-L	1901		
	LNCS Neo	2329		
	LNCS Inf	2328		
	LNCS NeoPt	2330		
	LNCS Neo-3	2320		
	LNCS Adtx-3	2317		
	LNCS Pdtx-3	2318		
	LNCS NeoPt-3	2321		
	LNCS Inf-3	2319		
	LNCS Trauma Adult	2411		
	LNCS Newborn Neo	2412		
	LNCS NeoPt-500	2331		
	LNCS Newborn Infant/Pediatric	2413		
	LNCS Adtx-3	2601		
	LNCS Pdtx-3	2602		
	LNCS Inf-3	2603		
	LNCS Neo-3	2604		
	LNCS NeoPt-3	2605		
	LNCS NeoPt-500	2606		
	LNCS E1	2918		
	LNCS Red TFA-1	3857		
	LNCS TFA-1	3858		
	LNCS Adtx	4714		
	LNCS Pdtx/Inf/Neo Sensor Kit	4715		

CO-086621

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52 Discovery
Irvine CA 92618

Product Family	Product Name	Part Number	UMDNS Code	GMDN Code
LNCS SET Reusable Sensors	LNCS TC-I	1895	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	LNCS DCI	1863		
	LNCS DCI-P	1864		
	LNCS TF-I	1896		
	LNCS YI	2258		
	LNCS DBI	2653		
	LNCS DCIv	2924		
	M-LNCS DCI	2501		
M-LNCS rainbow SET Disposable Sensors	R25-L	2219	17594 Probes, Oximeter	47581 Pulse Co-oximeter probe, single-use
	R20-L	2220		
	R20	2222		
	R 25	2221		
	R1 25L	2414		
	R1 20L	2415		
	R1 25	3792		
	R1 20	3793		
M-LNCS rainbow SET Reusable Sensors	rainbow DCIP-dc3	2069	17594 Probes, Oximeter	47582 Pulse Co-oximeter probe, reusable
	rainbow DCIP-dc12	2070		
	rainbow DCIP-dc8	2640		
	rainbow DCP-3 SC 200	2647		
	rainbow DCI	2696		
	rainbow DCIP	2697		
	rainbow DCI SC 200	3418		
	rainbow DCIP SC 200	3419		
	rainbow DCI SC 400	3420		
	rainbow DCIP SC 400	3421		
	rainbow DCI SC 1000	3647		
	rainbow DCIP SC 1000	3648		
	rainbow DCI-6	3657		
	rainbow DCIP-6	3658		
	rainbow DCI-mini SC 200	3797		
	rainbow DCI-mini SC 400	3798		
	rainbow DCI-mini SC 1000	3799		
	rainbow Super DCI-mini SC 200	4309		
	rainbow Super DCI-mini SC 400	4310		
	rainbow Super DCI-mini SC 1000	4311		
M-LNCS SET Disposable Sensors	M-LNCS Adtx	2508	17594 Probes, Oximeter	31658 Pulse oximeter probe, single-use
	M-LNCS Adtx-3	2509		
	M-LNCS Pdtx	2510		
	M-LNCS Pdtx-3	2511		
	M-LNCS Inf	2512		
	M-LNCS Inf-3	2513		
	M-LNCS Neo	2514		

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Irvine CA 92618

Product Family	Product Name	Part Number	UMDNS Code	GMDN Code
	M-LNCS Neo-3	2515		
	M-LNCS NeoPt	2516		
	M-LNCS NeoPt-3	2517		
	M-LNCS NeoPt-500	2518		
	M-LNCS E1	2919		
	M-LNCS Neo-L	3668		
	M-LNCS NeoPt-L	3669		
	M-LNCS Inf-L	3670		
	M-LNCS TFA-1	3856		
M-LNCS SET Reusable Sensors	M-LNCS DCI-P	2502	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	M-LNCS TC-I	2503		
	M-LNCS TF-I	2504		
	M-LNCS YI	2505		
	M-LNCS DBI	2507		
Rad-G Reusable Sensors	Rad-G Sensor	4325	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	Rad-G YI	4653		
RD rainbow SET Disposable Sensors	RD rainbow SET-2 Adt	4026	17594 Probes, Oximeter	47581 Pulse Co-oximeter probe, single-use
	RD rainbow SET-2 Pdt	4027		
	RD rainbow SET-2 Inf	4028		
	RD rainbow SET-2 Neo	4029		
	RD rainbow Lite SET-1 Adt	4042		
	RD rainbow Lite SET-1 Pdt	4043		
	RD rainbow Lite SET-1 Inf	4044		
	RD rainbow Lite SET-1 Neo	4045		
	RD rainbow Adt 8λ SpCO	4034		
	RD rainbow Pdt 8λ SpCO	4035		
	RD rainbow Inf 8λ SpCO	4036		
	RD rainbow Neo 8λ SpCO	4037		
	RD rainbow Adt 12λ SpHb SpCO	4038		
	RD rainbow Pdt 12λ SpHb SpCO	4039		
	RD rainbow Inf 12λ SpHb SpCO	4040		
	RD rainbow Neo 12λ SpHb SpCO	4041		
RD rainbow SET Reusable Sensors	LNCS-II rainbow DCI 8λ SpCO	4067	17594 Probes, Oximeter	47582 Pulse Co-oximeter probe, reusable
	LNCS-II rainbow DCIP 8λ SpCO	4068		
	LNCS-II rainbow DCI-6 8λ SpCO	4069		
	LNCS-II rainbow DCIP-6 8λ SpCO	4070		
	LNCS-II rainbow DCI 8λ SpHb SC 200	4058		
	LNCS-II rainbow DCIP 8λ SpHb SC 200	4061		
	LNCS-II rainbow DCI 8λ SpHb SC 400	4059		
	LNCS-II rainbow DCIP 8λ SpHb SC 400	4062		
	LNCS-II rainbow DCI 8λ SpHb SC 1000	4060		
	LNCS-II rainbow DCIP 8λ SpHb SC 1000	4063		

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Masimo
52 Discovery
Irvine CA 92618

Product Family	Product Name	Part Number	UMDNS Code	GMDN Code
RD SET Disposable Sensors	RD SET Adt	4000	17594 Probes, Oximeter	31658 Pulse oximeter probe, single-use
	RD SET Pdt	4001		
	RD SET Inf	4002		
	RD SET Neo	4003		
	RD SET NeoPt	4004		
	RD SET NeoPt-500	4005		
	RD SET Trauma	4011		
	RD SET Newborn Infant/Pediatric	4012		
	RD SET Newborn Neonatal	4013		
	RD SET Blue	4014		
	RD SET E1	4015		
	RD SET TFA-1	4016		
	RD SET Adt CS-2	4470		
	RD SET Pdt CS-2	4471		
	RD SET Inf CS-2	4472		
	RD SET Neo CS-2	4473		
	RD SET NeoPt CS-2	4474		
	RD SET Adt CS-3	4475		
	RD SET Pdt CS-3	4476		
	RD SET Inf CS-3	4477		
	RD SET Neo CS-3	4478		
	RD SET NeoPt CS-3	4479		
	RD SET Adt CS-1	4615		
	RD SET Neo CS-1	4886		
RD SET Reusable Sensors	RD SET DCI	4050	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	RD SET DCI-P	4051		
	RD SET TC-I	4053		
	RD SET YI	4054		
	RD SET TF-I	4055		
	RD SET DBI	4052		
Red SET Reusable Sensors	Red DCI-dc3	2053	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable
	Red DCI-dc12	2054		
	Red DCIP-dc12	2257		
	Red DCIP-dc3	2256		
	Red DBI-dc3	2643		
	Red DBI-dc8	2644		
SpO2.COM Sensors	SpO2.com A	1774	17594 Probes, Oximeter	31658 Pulse oximeter probe, single-use
	SpO2.com P	1775		
	SpO2.com N	1776		
	SpO2.com I	1777		
	SpO2.com RS-I	1778	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable

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

TÜV SÜD
Product Service

Certificate

No. Q5 092076 0026 Rev. 01

Holder of Certificate: **Masimo Corporation**
52 Discovery
Irvine CA 92618
USA

Certification Mark:

Scope of Certificate:

Design and Development, Production, Service and Distribution of:

- **Pulse Oximeters and Accessories (Cables and Sensors),**
- **Respiratory Monitors and Accessories (Cables and Sensors),**
- **EEG Monitors and Accessories (Cables and Sensors),**
- **Physiologic Monitoring Systems for Blood Pressure and Body Temperature,**
- **Capnography Monitors and Accessories (Sampling Lines and Cannulas).**

Design and Development, Production, Distribution and Installation of Telemetric Physiologic Monitoring System.

Design and Development, Production and Distribution of:
•ECG Monitors and Accessories (ECG Electrodes),
•Patient Position Monitoring System,
•Regional Oximeters and Accessories (Cables and Sensors).

Design and Development, Production, and Distribution of Blood Pressure Cuffs.

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 092076 0026 Rev. 01

Report No.: 72180133

Valid from: 2022-12-07
Valid until: 2024-12-20

Date, 2022-12-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

TÜV SÜD
Product Service

Certificate

No. Q5 092076 0026 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):

Masimo Corporation
52 Discovery, Irvine CA 92618, USA

Design and Development of: 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, and Blood Pressure Cuffs.

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

Production of Components for Pulse Oximeters and Accessories (Cables and Sensors) and Regional Oximeters and Accessories (Cables and Sensors). Receiving, Incoming Inspection and Storage of Raw Materials. Installation of Telemetric Physiologic Monitoring System.

Masimo Corporation
9600 Jeronimo, Irvine CA 92618, USA

Production and Distribution of Pulse Oximeters and Accessories (Cables and Sensors). Distribution of: 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, and Blood Pressure Cuffs.

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

Production and Service of: Pulse Oximeters and Accessories (Cables and Sensors), EEG Monitors and Accessories (Cables and Sensors), Physiologic Monitoring Systems for Blood Pressure and Body Temperature, Respiratory Monitors and Accessories (Cables and Sensors), Capnography Monitors and Accessories (Sampling Lines and Cannulas).

TÜV®

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

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Akkreditierungsstelle
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Production of: ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System, and Regional Oximeters and Accessories (Cables and Sensors) and Telemetric Physiologic Monitoring System.

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

Production of Pulse Oximeter Sensors.

Industrial Vallera de Mexicali S.A. de C.V.
Carretera Mexicali-Algodones # 4798 Int., 4-1, Col. Diez Division Dos, Baja California, 21395 Mexicali, MEXICO

Production of Pulse Oximeter Sensors and Accessories (Cables and Sensors), Telemetric Physiologic Monitoring System, EEG Monitors and Accessories (Cables and Sensors), Physiologic Monitoring Systems for Blood Pressure and Body Temperature, Respiratory Monitors and Accessories (Cables and Sensors), Capnography Monitors and Accessories (Sampling Lines and Cannulas) and Blood Pressure Cuffs.

Distribution of: Pulse Oximeters and Accessories, Telemetric Physiologic Monitoring System, EEG Monitors and Accessories (Cables and Sensors), Physiologic Monitoring Systems for Blood Pressure and Body Temperature, Respiratory Monitors and Accessories (Cables and Sensors), Capnography Monitors and Accessories (Sampling Lines and Cannulas), ECG Monitors and Accessories (ECG Electrodes), Patient Position Monitoring System and Blood Pressure Cuffs.

Masimo Corporation
15750 Alton Parkway, Irvine CA 92618, USA

Regulatory, CAPA, Complaints and Internal Audit.

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Direct Connect Sensors (for Rad-G Pulse Oximeter)

PN	Description	UM	Product Image
4325	Rad-G Reusable Sensor Adult/Pediatric/Infant Reusable Sensor, 3 ft. For direct connection with Rad-G Pulse Oximeter 1/box, non-sterile Weight ≥ 3 kg Not made with natural rubber latex	EA	
4653	Rad-G YI Sensor Multisite Reusable Sensor, 3 ft. For direct connection with Rad-G Pulse Oximeter 1/box, non-sterile Weight > 1 kg Includes 2 foam wraps Not made with natural rubber latex	EA