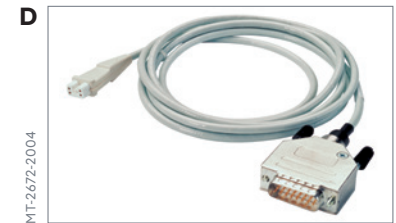


VENTILATION ACCESSORIES

SENSORS

A	Neonatal flow sensor ISO 15, PSU, sterilisable	8411130
B	Insert for neonatal flow sensor, PSU, sterilisable, 5 pcs.	8410179
C	Neonatal flow sensor cable for medical ventilators of the V series with Neo option and VN series	8416600
D	Neonatal flow sensor cable for Babylog 8000 and former Evita ventilators with Neo option	8409626



RESUSCITAIRE

RESUSCITAIRE

A	Skin temperature probe Premi-Probe 3, reusable	MU11225
B	Skin temperature probe Premi-Probe 3, disposable, 10 pcs.	MU11228
C	Cover for skin temperature probe CARE-FOR-ME, hydrogel, disposable, small, 100 pcs.	MU06944
D	Cover for skin temperature probe CARE-FOR-ME, hydrogel, disposable, large, 100 pcs.	MU06943
E	Mattress SoftBed, for Resuscitaire, reusable, with scale	MP01404
E	Mattress SoftBed, for Resuscitaire, reusable, without scale	MP01402



Drägerwerk AG & Co. KGaA, 23542 Lübeck, Germany

Our reference
739/22 // ew-de

To whom it may concern

Phone
+49 451 882-2471

E-mail
Erika.Wagner@draeger.com

November 24, 2025

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 at present 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 31.12.2026.

Drägerwerk AG & Co. KGaA



Digital unterschrieben von
Claus Martin Baumann
Datum: 2025.11.24
12:50:46 +01'00'

Claus Martin Baumann
Authorized Representative



Digitally signed by Tatjana
Engel
Date: 2025.11.25
12:25:29 +01'00'

Tatjana Engel
Authorized Representative



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

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: NOLADE2ISPL

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
UID-Nr. DE135082211

Chairwoman of the Supervisory Board for
Drägerwerk AG & Co. KGaA: Maria Dietz
Chairman of the Supervisory Board for
Drägerwerk Verwaltungs AG: Stefan Lauer

Executive Board:
Stefan Dräger (chairman)
Stefanie Hirsch
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆ 認 證 證 書 ◆ CERTIFICATE ◆ ZERTIFIKAT



Management Service

CERTIFICATE

Certificate Registration No.: 12 100 49423 TMS / Order No.: 707037695

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that the organization

Dräger

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

for the scope

**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;
Design, development and distribution of products and services to
support healthcare workflows**

including the sites see enclosure

has established and applies a Quality Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2024-01-15** until **2027-01-14**.

Fred Wenke
Head of Certification Body
Munich, 2023-12-14

Page 1 of 2





Management Service

ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100 49423 TMS / Order No.: 707037695

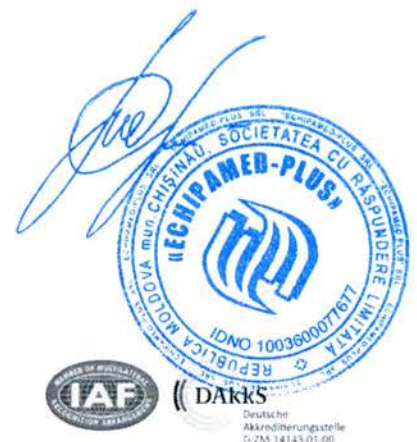
certificate holder:

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

at the sites	scope
Drägerwerk AG & Co. KGaA Moislinger Allee 53-55 23542 Lübeck Germany	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; Design, development and distribution of products and services to support healthcare workflows
Drägerwerk AG & Co. KGaA Revalstraße 1 23560 Lübeck Germany	Production and distribution of diagnostic and therapeutic medical devices and installations

Fred Wenke
 Head of Certification Body
 Munich, 2023-12-14

Page 2 of 2





Certificate

No. Q5 010578 0031 Rev. 02

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

Certification Mark:



Scope of Certificate: **Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations 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 and sterile Equipment for 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. 02

Report No.: 713308726
Valid from: 2024-01-14
Valid until: 2027-01-13

Date, 2023-12-28

C. Dicks

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q5 010578 0031 Rev. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Drägerwerk AG & Co. KGaA**
Moisinger Allee 53-55, 23542 Lübeck, GERMANY

Design, Development, Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations 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 and sterile Equipment for Medical Lights

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

Manufacture and Distribution of Diagnostic and Therapeutic Medical Devices as well as Installations 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 and sterile Equipment for Medical Lights





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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zgl.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. 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](http://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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-03





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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

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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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

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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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:


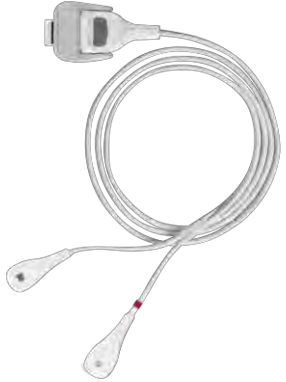
Rev.	Dated	Report	Description
00	2020-03-18	713169482	-
01	2021-07-02	713184148	-
02	2021-09-30	713215188	-
03	2021-10-01	713215832	-
04	2021-10-04	713215842	-
05	2021-10-04	713219421	-
06	2021-11-22	713229134	-
07	2022-02-21	713213004	-
08	2022-10-06	713225304_CN	-
09	2023-03-14	713253108_CN	Supplemented: 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








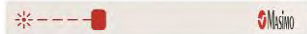

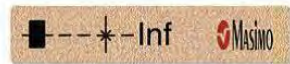
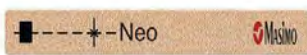



Red LNC Patient Cables (for use with Masimo rainbow SET Devices)

PN	Description	UM	Product Image
4252	Red LNC M20-04 LNCS Series M20 SpO ₂ Patient Cable, 4 ft.	EA	
4253	Red LNC M20-10 LNCS Series M20 SpO ₂ Patient Cable, 10 ft.	EA	
2055	Red LNC-04 LNCS Series 20-pin SpO ₂ Patient Cable, 4 ft.	EA	
2056	Red LNC-10 LNCS Series 20-pin SpO ₂ Patient Cable, 10 ft.	EA	
3630	Red 25 LNC-4 LNCS Series 25-pin SpO ₂ Patient Cable, 4 ft	EA	
3376	Red 25 LNC-4RA LNCS Series 25-pin SpO ₂ Patient Cable with Right Angle Connector, 4 ft	EA	
3345	Red 25 LNC-10 LNCS Series 25-pin SpO ₂ Patient Cable, 10 ft	EA	



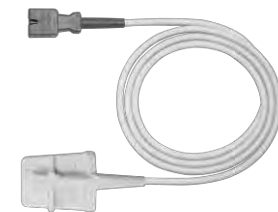



Direct Connect Sensors (for Rad-G Pulse Oximeter)

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	 A white cable with a rectangular connector at one end and a sensor probe at the other. The sensor probe has two small red LEDs. The cable is coiled.
4653	<p style="background-color: yellow;">Rad-G YI Sensor</p> <p style="background-color: yellow;">Multisite Reusable Sensor, 3 ft.</p> <p style="background-color: yellow;">For direct connection with Rad-G Pulse Oximeter</p> <p style="background-color: yellow;">1/box, non-sterile</p> <p style="background-color: yellow;">Weight > 1 kg</p> <p style="background-color: yellow;">Includes 2 foam wraps</p> <p style="background-color: yellow;">Not made with natural rubber latex</p>	EA	 A white cable with a rectangular connector at one end and two sensor probes at the other. One probe has a red LED. The cable is coiled.



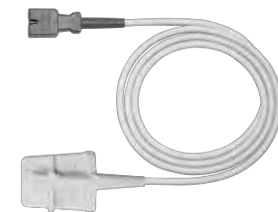



Sensor Accessories

PN	Description	UM	Product Image
4439	RD rainbow SET Inf Replacement Tapes For use with RD rainbow Inf sensors 50 / box, non-sterile Not made with natural rubber latex	EA	
4440	RD rainbow SET Neo Replacement Tapes For use with RD rainbow SET Neo sensors 50 / box, non-sterile Not made with natural rubber latex	EA	
4046	RD SET Inf Replacement Tapes For use with RD SET Inf/Inf CS-2/Inf CS-3, RD SET Blue, and RD rainbow Lite SET Inf 102 / box, non-sterile Not made with natural rubber latex	Box	
4047	RD SET Neo Replacement Tapes For use with RD SET Neo CS-3 102 / box, non-sterile Not made with natural rubber latex	Box	
4674	Neo Replacement Tapes For use with Radius PPG Neo, RD rainbow Neo 4A, RD SET Neo/Neo CS-2/Neo CS-1, RD rainbow Lite SET Neo Also available for use with RD SET Neo CS-3 102/box, non-sterile Not made with natural rubber latex	Box	
4048	RD SET SofTouch™ Replacement Wraps For use with RD SET NeoPt/NeoPt CS-2/NeoPt CS-3, RD SET Trauma, RD SET Newborn Neonatal 10 / pack, non-sterile Not made with natural rubber latex	Pack	
4094	RD SET NeoPt-500 SofTouch Replacement Wraps For use with RD SET NeoPt-500/NeoPt-500 CS-2/NeoPt-500 CS-3 and Newborn Infant/Pediatric 10 / pack, non-sterile Not made with natural rubber latex	Pack	
2307	LNCS Replacement Tapes for Inf Series Sensors For use with LNCS Inf/Inf-3 102 / box, non-sterile Not made with natural rubber latex	Box	
2308	LNCS Replacement Tapes for Neo Series Sensors For use with LNCS Neo/Neo-3 102 / box, non-sterile Not made with natural rubber latex	Box	
2309	LNCS Replacement SofTouch Wraps for NeoPt, NeoPt-3, Trauma and Newborn Neonatal Sensors For use with LNCS NeoPt/NeoPt-3, Trauma and Newborn Neonatal 10 / pack, non-sterile Not made with natural rubber latex	Pack	
2322	LNCS Replacement SofTouch Wraps for NeoPt-500 and Newborn Infant / Pediatric Sensors For use with LNCS NeoPt-500 and LNCS Newborn Infant/Pediatric 10 / pack, non-sterile Not made with natural rubber latex	Pack	
1602	Foam Wrap For use with YI Sensors 12 / pack, non-sterile Not made with natural rubber latex	Pack	






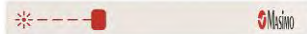


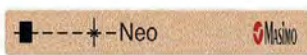



LNCS Reusable Sensors

PN	Description	UM	Product Image
1863	<p>LNCS DCI Adult Reusable Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.</p>	EA	
1864	<p>LNCS DCI-P Pediatric Reusable Sensor, 3 ft. 1 / box, non-sterile Weight 10 kg – 50 kg Not made with natural rubber latex.</p>	EA	
2653	<p>LNCS DBI Adult Soft Reusable Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.</p>	EA	
1895	<p>LNCS TC-I Reusable Tip-Clip EAR Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.</p>	EA	
1896	<p>LNCS TF-I Adult Transreflectance Forehead, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.</p>	EA	
2258	<p>LNCS YI Multisite Reusable Sensor, 3 ft. 1 / box, non-sterile Multiple Foam and Adhesive Wraps Weight > 1 kg Not made with natural rubber latex.</p>	EA	

LNCS Reusable Sensors

PN	Description	UM	Product Image
1863	LNCS DCI Adult Reusable Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.	EA	
1864	LNCS DCI-P Pediatric Reusable Sensor, 3 ft. 1 / box, non-sterile Weight 10 kg – 50 kg Not made with natural rubber latex.	EA	
2653	LNCS DBI Adult Soft Reusable Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.	EA	
1895	LNCS TC-I Reusable Tip-Clip EAR Sensor, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.	EA	
1896	LNCS TF-I Adult Transreflectance Forehead, 3 ft. 1 / box, non-sterile Weight > 30 kg Not made with natural rubber latex.	EA	
2258	LNCS YI Multisite Reusable Sensor, 3 ft. 1 / box, non-sterile Multiple Foam and Adhesive Wraps Weight > 1 kg Not made with natural rubber latex.	EA	

Sensor Accessories

PN	Description	UM	Product Image
4439	RD rainbow SET Inf Replacement Tapes For use with RD rainbow Inf sensors 50 / box, non-sterile Not made with natural rubber latex	EA	
4440	RD rainbow SET Neo Replacement Tapes For use with RD rainbow SET Neo sensors 50 / box, non-sterile Not made with natural rubber latex	EA	
4046	RD SET Inf Replacement Tapes For use with RD SET Inf/Inf CS-2/Inf CS-3, RD SET Blue, and RD rainbow Lite SET Inf 102 / box, non-sterile Not made with natural rubber latex	Box	
4047	RD SET Neo Replacement Tapes For use with RD SET Neo CS-3 102 / box, non-sterile Not made with natural rubber latex	Box	
4674	Neo Replacement Tapes For use with Radius PPG Neo, RD rainbow Neo 4A, RD SET Neo/Neo CS-2/Neo CS-1, RD rainbow Lite SET Neo Also available for use with RD SET Neo CS-3 102/box, non-sterile Not made with natural rubber latex	Box	
4048	RD SET SofTouch™ Replacement Wraps For use with RD SET NeoPt/NeoPt CS-2/NeoPt CS-3, RD SET Trauma, RD SET Newborn Neonatal 10 / pack, non-sterile Not made with natural rubber latex	Pack	
4094	RD SET NeoPt-500 SofTouch Replacement Wraps For use with RD SET NeoPt-500 /NeoPt-500 CS-2/NeoPt-500 CS-3and Newborn Infant/Pediatric 10 / pack, non-sterile Not made with natural rubber latex	Pack	
2307	LNCS Replacement Tapes for Inf Series Sensors For use with LNCS Inf/Inf-3 102 / box, non-sterile Not made with natural rubber latex	Box	
2308	LNCS Replacement Tapes for Neo Series Sensors For use with LNCS Neo/Neo-3 102 / box, non-sterile Not made with natural rubber latex	Box	
2309	LNCS Replacement SofTouch Wraps for NeoPt, NeoPt-3, Trauma and Newborn Neonatal Sensors For use with LNCS NeoPt/NeoPt-3, Trauma and Newborn Neonatal 10 / pack, non-sterile Not made with natural rubber latex	Pack	
2322	LNCS Replacement SofTouch Wraps for NeoPt-500 and Newborn Infant / Pediatric Sensors For use with LNCS NeoPt-500 and LNCS Newborn Infant/Pediatric 10 / pack, non-sterile Not made with natural rubber latex	Pack	
1602	Foam Wrap For use with YI Sensors 12 / pack, non-sterile Not made with natural rubber latex	Pack	



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 Trandafilui 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





- 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, commission 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*



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Masimo Corporation

Main site: 52 Discovery, Irvine, California, 92618, United States

Additional sites are detailed in the attached appendix

has been registered by Intertek as conforming to the requirements of

EN ISO 13485:2016

The management system is applicable to:

Design and development, manufacture, servicing 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); ECG monitors and accessories (ECG electrodes); patient monitoring devices (cables and sensors); gas monitoring devices and accessories (sampling lines and cannulas); and hemodynamic monitoring systems and accessories (cables) for the area of respiratory care and anesthesia.

Design and development, manufacture, installation, servicing and distribution of telemetric physiologic monitoring systems for the area of respiratory care and anesthesia.

Design and development, manufacture and distribution of regional oximeters and accessories (cables and sensors); blood pressure cuffs; compact multi-gas sensors; and percutaneous nerve stimulators for the area of respiratory care and anesthesia

Certificate Number:

0113397

Revision:

07

Initial Certification Date:

30 April 2021

Date of Certification Decision:

4 December 2024

Certificate Valid Date:

4 December 2024

Certificate Expiry Date:

10 May 2027



Akcred. nr. 10426
Certifiering av ledningssystem
ISO/IEC 17021-1



Intertek

Brian Mather

Certification Authority, Intertek Medical
Notified Body AB

Intertek Medical-Notified Body AB
P.O. Box 1103, SE-164 22 Kista, Sweden





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



CO-086621



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		





Masimo
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 Amtx	2508	17594 Probes, Oximeter	31658 Pulse oximeter probe, single-use
	M-LNCS Amtx-3	2509		
	M-LNCS Pmtx	2510		
	M-LNCS Pmtx-3	2511		
	M-LNCS Inf	2512		
	M-LNCS Inf-3	2513		
M-LNCS Neo	2514			





Masimo
52 Discovery
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		
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 Y1	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-1	1778	17594 Probes, Oximeter	37808 Pulse oximeter probe, reusable





41473 WATER EJECTOR 3/4 " - 3/4" -1 "BRASS SC500 (10)


Gross Weight: 1.523 KG, Dimensions: 5x3.500x27.500CM

 Descripción larga



41772 JOINT WITH POSITIONER, OF STEAM GENERATORS OF KLINGER GRAFIT S101/
SC500PSM-LAMINATED 20010

Gross Weight: 0.034 KG, Dimensions: 32x0.200x26CM

 Descripción larga

Barcelona, December 4th, 2025

TO WHOM IT MAY CONCERN

Whereas **ANTONIO MATACHANA, S.A** who are established and reputable manufacturers of Infection Control equipment, with headquarters in C/ Copèrnic, 8 08860 Castelldefels – Barcelona (Spain), do hereby certify that the company

**Echipamend Plus SRL,
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau**

is our distributor in Moldova and in therefore authorized by us to offer, sell, deliver, install, repair and service Matachana equipment in Moldova.

This sole agency agreement will be valid until the 31st of December 2026; renewable in written form, under mutual approval.

And in proof of this, we hereunder sign the present certificate in the city of Barcelona, on the 4th of December 2026.



ANTONIO MATACHANA, S.A

Mr. Manuel Matachana

CEO



Certificate of Approval

This is to certify that the Management System of:

Antonio Matachana, S.A.

C/ Copérnic, 8, 08860 Castelldefels, Barcelona, Spain

has been approved by LRQA to the following standards:

ISO 9001:2015

Approval number(s): ISO 9001 – 0036999

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, manufacture and final testing of sterilizers, disinfection and treatment equipment for medical devices, food, research, industry, medical waste and pharmaceutical laboratories. Analysis of material compatibility with sterilization processes. Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Technical and validation service for clients (sterilizers, washer-disinfectors and sealers). Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment. Commercial activities and after sales service.

Marta Escudero

Regional Director, Europe

Issued by: LRQA Limited



Certificate Schedule

Location	Activities
<p>Antonio Matachana, S.A. C/ Copèrnic, 8, 08860 Castelldefels, Barcelona, Spain</p>	<p>ISO 9001:2015 Design, manufacture and final testing of sterilizers, disinfection and treatment equipment for medical devices, food, research, industry, medical waste and pharmaceutical laboratories. Analysis of material compatibility with sterilization processes. Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Technical and validation service for clients (sterilizers, washer-disinfectors and sealers). Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment.</p>
<p>Antonio Matachana, S.A. C/ Raurell 21-29 Nave 4, 08860 Castelldefels, Barcelona, Spain</p>	<p>ISO 9001:2015 Technical and validation service at customer's premises (sterilizers, washer-disinfectors and sealing machines).</p>
<p>Antonio Matachana, S.A. C/ Can Balmes, 1, 08460 Santa Maria de Palautordera, Barcelona, Spain</p>	<p>ISO 9001:2015 Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment.</p>
<p>Antonio Matachana, S.A. C/ Raurell 21-29 Nave 1, 08860 Castelldefels, Barcelona, Spain</p>	<p>ISO 9001:2015 Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Analysis of material compatibility with sterilization processes.</p>
<p>Matachana France, S.A. Europarc 5, Allée des Saules, 94043 Créteil Cedex, France</p>	<p>ISO 9001:2015 Commercial activities and after sales service.</p>



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1297087-1

Certificate Holder: ANTONIO MATACHANA, S.A.
C/ Copèrnic 8
08860 Castelldefels, Barcelona
Spain

Scope: Design and development, manufacture, distribution,
installation and servicing of sterilizers and disinfection devices.

Distribution of equipment for sterilization and disinfection.

Validation service for sterilization process with moist heat
and low temperature steam and formaldehyde (LTSF)
for washing and thermal disinfection processes and for heat
sealing processes of packaging for terminally sterilized
devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92718020-90

Effective date: 2024-02-18

Expiry date: 2027-02-17

Issue date: 2024-02-16

Replaces certificate SX 1297087-1 issued 2023-07-13

This certificate can be validated on <https://www.certifiedia.com>


Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1297087-1
Certificate Holder: ANTONIO MATACHANA, S.A.
C/ Copèrnic 8
08860 Castelldefels, Barcelona
Spain

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	ANTONIO MATACHANA, S.A. C/ Copèrnic 8 08860 Castelldefels, Barcelona Spain	Design and development, manufacture, distribution, installation and servicing of sterilizers and disinfection devices. Distribution of equipment for sterilization and disinfection. Validation service for sterilization process with moist heat and low temperature steam and formaldehyde (LTSF) for washing and thermal disinfection processes and for heat sealing processes of packaging for terminally sterilized devices
/02	ANTONIO MATACHANA, S.A. Raurell 21-29, Nave 1 and 4 08860 Castelldefels, Barcelona Spain	Distribution, installation and servicing of sterilizers and disinfection devices. Distribution of equipment for sterilization and disinfection. Validation service for sterilization process with moist heat and low temperature steam and formaldehyde (LTSF) for washing and thermal disinfection process and for heat sealing processes of packaging for terminally sterilized devices.
/03	ANTONIO MATACHANA, S.A. Almogívers 174 08018 Barcelona Spain	Distribution of equipment for sterilization and disinfection.
/04	ANTONIO MATACHANA, S.A. C/ Can Balmes 1 08460 Santa Maria de Palautordera, Barcelona Spain	Manufacture of sterilizer components.

Report No.: 92718020-90
Effective date: 2024-02-18
Expiry date: 2027-02-17
Issue date: 2024-02-16

This certificate can be validated on <https://www.certipedia.com>


Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



EC CONFORMITY CERTIFICATE

The manufacturer Antonio Matachana, S.A., located at Carrer Almogàvers, 174, E-08018 Barcelona (Spain), CERTIFIES:

That the steam sterilizers Matachana brand, SC500 series, models:

SC500V-1 SC500V-2 SC501V-1 SC501V-2 SC502V-1 SC502V-2
SC500E-1 SC500E-2 SC501E-1 SC501E-2 SC502E-1 SC502E-2

being products within the scope of the European Directive 93/42/EEC concerning medical devices and classified to class IIb according to the rule 15 of the Annex IX, are in conformity with:

- Directive 93/42/EEC concerning medical devices, Annex I, according to the harmonized standard:

EN 285

- The more specific essential health and safety requirements of the Annex I of the Directive 2006/42/EC on machinery, according to the following harmonized standards:

EN ISO 12100

EN 60204-1

The conformity assessment according to Directive 93/42/EEC concerning medical, Annex II except II.4, with registration number HD 60144134 0001 from the European Notified Body TÜV Rheinland LGA Products GmbH located at Tillystrasse 2, D-90431 Nürnberg, allows to fix on each manufactured product, the CE0197 marking and to draw up the related EC conformity declaration.

- Directive 2014/68/EU concerning pressure equipment according to the following harmonized standards:

EN 13445

EN 14222

The conformity assessment according to Directive 2014/68/EU concerning pressure equipment, module B+C2 (EU-type examination-production type + conformity to type), with certificate number ATI/EP-B/B04902/12 from the European Notified Body TÜV SÜD ATISAE, S.A.U located in Avda. de los Artesanos, 20, E-28760 Tres Cantos, Madrid (Spain), allows to fix on each manufactured product, the CE0053 marking and to draw up the related EC conformity declaration.

- Essential requirements set out in Annex I of the European Directive 2014/30/UE relating to electromagnetic compatibility according to the following standard:

EN 61326-1

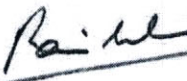
- Principal elements on the safety objectives set out in Annex I of the European Directive 2014/35/UE relating to electrical equipment designed for use within certain voltage limits according to the following standards:

EN 61010-1

EN 61010-2-040

- Additionally, these products comply with the European Directive 2011/65/UE on restriction of the use of certain hazardous substances in electrical and electronic equipment.

Barcelona, May 11th, 2021


Ramón Calvera Sagú
ANTONIO MATACHANA, S.A.
Director of Quality and of Research & Technology

ANTONIO MATACHANA, S.A.
C/ Almogàvers, 174
08018 - BARCELONA

NOTE: For undated normative references, the latest edition of the referenced document (including any amendments) applies.





Sysmex Europe SE · Deelbøge 19 D · 22297 Hamburg · Germany

To whom it may concern

Sysmex Europe SE
Deelbøge 19 D
22297 Hamburg, Germany
Phone +49 40 527 26-0
Fax +49 40 527 26-100
info@sysmex-europe.com

LETTER OF AUTHORIZATION

Whereas Sysmex Europe SE, who are established, reputable and authorised representative in Europe, Middle East and Africa (EMEA region), officially announced by the manufacturer Sysmex Corporation, having its principal place of business at 4-4-4 Takatsukadai, Nishi-ku, Kobe 651- 2271, Japan, and having the power to grant authorizations to local representatives within the above mentioned markets, do hereby declare that the company

do hereby declare that the company

ECHIPAMED Plus SRL
Valea Trandafirilor 24 "B", off. 80
MD-2001 Chisinau, Moldova (the "COMPANY")

is our distributor and local representative for the following Sysmex products:

Sysmex Haematology- and Urine- Analysers
with Reagents, Accessories, Software and Spare Parts
(the "**Products**")

In the territory of Moldova (the "**TERRITORY**")

The **COMPANY** is therefore authorized to carry out all commercial and support activities for the **PRODUCTS** including sales, marketing, application, registration and field service support in the **TERRITORY**.

The **COMPANY** is aware that this special authorisation is limited to the above listed **PRODUCTS** and does not create any further rights for the **COMPANY**.

We hereby grant our warranty following our general conditions of sale for the **PRODUCTS** delivered, consisting of and limited to:

Free of charge supply of spare parts to the **COMPANY** as replacement for defective new parts for a period of 14 months after B/L - AWB date.

08/2005



Company registered at
District Court Hamburg under
HRB 193509
VAT-ID DE 118 687 842
WEEE/ElektroG Reg. Nr. DE 159 56 453

Chairman of the
Supervisory Board
Iwane Matsui

Management Board
Alain Baverel (CEO)
Yuki Hyogu
Dr Sanjeev Kumar
Stefanie Schaal
Matthias Völkel

COMMERZBANK AG
Hamburg
IBAN DE20 2004 0000 0287 1879 00
SWIFT/BIC COBADEFFXXX

www.sysmex-europe.com





This declaration is valid until 31 March 2027 and may be revoked unilaterally by Sysmex in writing before that date for due cause. Such due cause shall, among others, be the termination or expiration of the distributorship relationship, if any, between Sysmex and the **COMPANY**.

On behalf of Sysmex Europe SE

Date: March 2, 2026

Place: 22297 Hamburg, Germany



Matthias Voelkel
Senior Executive Officer
Member of Management Board



Sysmex Europe SE
Deelbøge 19 D
22297 Hamburg

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

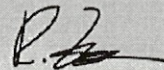
Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents, laboratory information system and gene variants analysis set (for cancer genome profiling)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-08-01 until 2027-07-31.
First certification 1998

2024-07-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1254782-1

Certificate Holder: SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori,
Chuo-ku, Kobe
651-0073 Japan

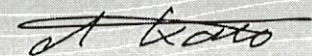
Scope: Design and development, manufacture, distribution,
installation and service of blood analyzer, urine analyzer,
related reagents and accessories and gene variants analysis
set (for cancer genome profiling)
Product categories: Analyzers and reagents for hematological
test, blood coagulation test, immune serum test, biochemical
test, genetic test, bacteriological test and urine test

Installation is not applicable for reagents and gene variants
analysis set (for cancer genome profiling)

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies
a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality
management system is subject to yearly surveillance.

Report No.: 150287325-301
Effective date: 2024-08-01
Expiry date: 2027-07-31
Issue date: 2024-07-04
Replaces certificate SX 1254782-1 issued 2023-08-28



Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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EC Declaration of Conformity

Application of Council Directive:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices,
- 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its related amending directives including the (EU) 2015/863 amending Annex II of the Directive 2011/65/EU,
- 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment.

Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,
- Directive 2011/65/EU based on the conformity assessment procedure in accordance with EN IEC 63000: 2018,
- Directive 2014/53/EU based on the conformity assessment procedures using harmonized standards EN 50364:2010, EN 61010-2-101:2002, EN 61326-2-6:2006, EN 301 489-1 V2.2.0, EN 301 489-3 V2.1.1 and EN 300 330 V2.1.1 in accordance with Annex II Conformity Assessment Module A

Product identification:

Product name: Automated Hematology Analyzer XN series
System Name: XN-1000, XN-1500, XN-2000, XN-3000, XN-3100, XN-9000, XN-9100, XN-9200
Model name: XN-10, XN-20
Accessories: SA-01*, SA-10*, SA-20*, SA-21*, SA-30*, SA-31*, BT-40*, CV-50*, CV-55*, CV-60*, CV-65*, CV-70*, ST-40*, ST-41*, ST-42*, TU-40*, RR-10*
Classification: Other device (except Annex II and self-testing devices)

*Conformity to 2014/53/EU does not apply

List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

Legal Manufacturer:

Name: SYSMEX CORPORATION
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised officer: Takashi Demachi Date: Sep. 15, 2021
Takashi Demachi, Executive Vice President

Authorised representative:

Name: SYSMEX EUROPE GMBH
Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: [Signature] Date: 29/09/2021
Sinem Yaman, Vice President, Head of Regulatory Affairs,
Quality Assurance, Quality Control

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Tel. +81-78-265-0500 Fax. +81-78-265-0524

www.sysmex.co.jp

