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 104938 0004 Rev. 00

Manufacturer:

MIPM Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Str. 6
82291 Mammendorf
GERMANY

SRN Manufacturer: DE-MF-000007654

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 104938 0004 Rev. 00

Report No.: 713210868

Valid from: 2022-05-12
Valid until: 2027-05-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-12

Digitally signed by Prodan Sveatoslav
Date: 2025.06.20 11:53:02 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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No. G10 104938 0004 Rev. 00

Classification:	IIa
Device Group:	Z1203019001 - NEUROMUSCULAR RELAXATION MONITORING EQUIPMENT
Intended Purpose:	n/a
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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

TÜV®

EC DECLARATION OF CONFORMITY

Medical Device Directive 93/42/EEC

We hereby declare under sole responsibility that the product

MRI Patient Monitoring System
Tesla^{M3}

Class: IIb (93/42/EEC, Annex IX, Rule 10)
UMDNS No.: 12-636 (physiological monitoring system)
GMDN Code: 61161 (MRI-patient physiologic monitoring system)

is in compliance with the essential requirements (Annex I)
of the Medical Device Directive 93/42/EEC

This declaration is valid for the mentioned product marked with the CE-mark.
The sole responsibility for issuing this declaration has

MIPM MAMMENDORFER INSTITUT
FÜR PHYSIK UND MEDIZIN GMBH
Oskar-von-Miller Str. 6
82291 Mammendorf
GERMANY

The company is assessed according to Directive 93/42/EEC, Annex II and ISO 13485:2016 (EN ISO 13485:2016) by the following Notified Body:
TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich (Germany), identification number 0123.
This declaration of conformity is valid in combination with the following certificate:
EC Certificate No. G1 104938 0002 valid until 10. May 2024

Mammendorf, 21. May 2021 .....
Jennifer Rosenheimer (Managing Director)

MRI Patient Monitoring System ***Tesla^{M3}*** consists of:

Item number	Description
1800001	MRI Patient Monitor (Basic configuration: ECG, Pulse Oximetry; Non-invasive blood pressure)
5450012	Option: Remote Monitor
5200057	Option: Invasive Blood Pressure 1
5200058	Option: Invasive Blood Pressure 2
5800001	Option: Temperature 1
5800002	Option: Temperature 2
5400038	Option: Multigas: Capnography, Oxygen, Anesthetic Agents
5450014	Option: Gating for Siemens MR Scanner
5000002	Option: Anesthesia View

Accessories/Components:

Item number	Description
ECG	
5300028	Wireless ECG Sensor for TeslaM3
5300202	ezPad MRI - MRI ECG Electrodes (S)
5300203	ezPad MRI - MRI ECG Electrodes (L)
5300006	NUPREP Gel
5300025	ECG Electrodes for MRI
SpO_2	
5010100	Wireless Pulse Oximetry Sensor for Tesla M3
5010012	SpO2 adapter - Basic (1x adult / 1x pediatric / 1x neonate)
5010022	SpO2 adapter large/adult (10x)
5010023	SpO2 adapter medium/pediatric (10x)
5010024	SpO2 adapter small/neonate (10x)
NIBP	
5100044	NIBP Pressure hose
5100038	NIBP Pressure cuff 9-15 cm
5100039	NIBP Pressure cuff 14-21,5 cm
5100040	NIBP Pressure cuff 20,5-28,5 cm
5100041	NIBP Pressure cuff 27-35 cm
5100042	NIBP Pressure cuff 34-44 cm
5100043	NIBP Pressure cuff 42-52 cm

Item number	Description
IBP	
5200031	IBP Interface cable – General
5200059	IBP Interface cable – Utah
5200062	IBP Interface cable – Medex MX980
5200063	IBP Interface cable – PvB 6300
5200064	IBP Interface cable – Medex MX960
5200066	IBP Interface cable – PvB XTRANS
5200067	IBP Interface cable – BD/Ohmeda
5200068	IBP Interface cable – Edwards/Baxter
5200069	IBP Interface cable – Transpac
Gas	
5400017	Gas Sample Line Set = 10 pcs.
5400036	Gas Water Trap = 12 pcs.
Temperature	
6210031	Fiber Optic Temperature Sensor Core
6210032	Fiber Optic Temperature Sensor Surface
Gating	
5450015	Gating Cable Siemens