



**Tesla<sup>M3</sup>**

**EC Declaration of  
Conformity**

# EC DECLARATION OF CONFORMITY

**Medical Device Directive 93/42/EEC**

We hereby declare under sole responsibility that the product

**MRI Patient Monitoring System**

**Tesla<sup>M3</sup>**

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

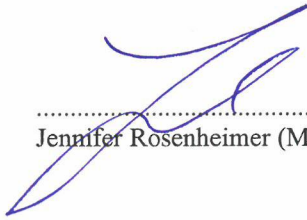
The company is assessed according to Directive 93/42/EEC, Annex II and ISO 13485:2016 (EN ISO 13485:2016) by the  
following Notified Body:

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

  
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Jennifer Rosenheimer (Managing Director)



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MRI Patient Monitoring System **Tesla<sup>M3</sup>** 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
<b>ECG</b>	
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
<b>SpO<sub>2</sub></b>	
5010100	Wireless Pulse Oximetry Sensor for Tesla M3
5010012	SpO <sub>2</sub> adapter - Basic (1x adult / 1x pediatric / 1x neonate)
5010022	SpO <sub>2</sub> adapter large/adult (10x)
5010023	SpO <sub>2</sub> adapter medium/pediatric (10x)
5010024	SpO <sub>2</sub> adapter small/neonate (10x)
<b>NIBP</b>	
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



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<b>Item number</b>	<b>Description</b>
<b>IBP</b>	
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
<b>Gas</b>	
5400017	Gas Sample Line Set = 10 pcs.
5400036	Gas Water Trap = 12 pcs.
<b>Temperature</b>	
6210031	Fiber Optic Temperature Sensor Core
6210032	Fiber Optic Temperature Sensor Surface
<b>Gating</b>	
5450015	Gating Cable Siemens