



TOF^{3D}⊛

**EC Declaration
of Conformity**

EC DECLARATION OF CONFORMITY

Medical Device Directive 93/42/EEC

We hereby declare under sole responsibility that the product

Neuromuscular Transmission Monitor

TOF^{3D}⊛

Class: IIa (93/42/EEC, Annex IX, Rule 10)

UMDNS No.: 16-250 (Stimulator, neuromuscular, functional)

GMDN Code: 35722 (Block-monitoring peripheral nerve electrical stimulation 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 from 01. February 2021 until 10. May 2024



Mammendorf, 02. February 2021

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Jennifer Rosenheimer (Managing Director)