UE DECLARATION OF CONFORMITY

According to annexe IV of the regulation (UE) 2017/745 on medical devices

The manufacturer,

IDMED, S.A.S.

Hôtel Technoptic, 2 rue Marc Donadille
13013 – Marseille – France
Single Registration Number (SRN): FR-MF-000002402

Declares and certifies, under its sole responsibility, that the device:

Accessories of the ToFscan (NeuroMuscular Transmission Monitor) & WiTOF (NeuroMuscular Transmission Station) devices

with the following references are compliant with:

- the Directive 2017/2102 of the European Parliament and of the Council of 15 November 2017 and the Directive 2015/863 of 31 March 2015 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS3)
- the General safety and performance requirements of the Regulation (UE) 2017/745
- the following harmonized standards:
- IEC 60601-1: 2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-6: 2013 - Ed. 3.1 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015-Ed. 1.1 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
- ISO 10993-1: 2009: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

REFERENCE	IUD-DI	DESCRIPTION
TOF-CHAR	3665023000108	AC Power / Charger (European electrical sockets Type C)
TOF-CHAR_UK	3665023000115	AC Power / Charger (UK electrical sockets Type G)
TOF-CHAR_US	3665023000122	AC Power / Charger (US electrical sockets Type A)
TOF-CHAR_C8	3665023000139	AC Power / Charger (C8 electrical sockets)
TOF-CHAR_C8_KR	3665023000443	AC Power / Charger (C8 electrical sockets) with Korea socket

TOF-CHAR_C8_BR	3665023000436	AC Power / Charger (C8 electrical sockets) with Brazil socket
TOF-CHAR_TI	3665023000146	AC Power / Charger (electrical sockets Type I)

According to the annex VIII of the Regulation (UE) 2017/745, these accessories are Class I rule 12.

REFERENCE	IUD-DI	DESCRIPTION
TOF-STICKER1	3665023000412	Double-sided stickers for eyebrow sensor (96 units)

According to the annex VIII of the Regulation (UE) 2017/745, the above accessory is Class I rule 1.

The Intended purpose of these accessories are to be used with the device to monitor the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.

The declaration is based on following elements:

- Technical file DT_TOFSCAN attesting the compliance to the General safety and performance requirements of the Regulation (UE) 2017/745

Marseille, 2021/05/26

Frederic BERNERT – President