

EC DECLARATION OF CONFORMITY

According to annexe VII of the council directive 93/42/EEC regarding medical devices

The manufacturer,

IDMED,

Hôtel Technoptic, 2 rue Marc Donadille

13013 – Marseille – France

Declares and certifies, under its sole responsibility, that the

accessories of the ToFscan & WiTOF devices:

with the following references are compliant with:

- the essential requirements of the Directive 93/42/EEC, its amendments and the French Public Health Code
- 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	DESCRIPTION
TOF-CHAR	AC Power / Charger (European electrical sockets Type C)
TOF-CHAR_UK	AC Power / Charger (UK electrical sockets Type G)
TOF-CHAR_US	AC Power / Charger (US electrical sockets Type A)
TOF-CHAR_C8	AC Power / Charger (C8 electrical sockets)
TOF-CHAR_C8_KR	AC Power / Charger (C8 electrical sockets) with Korea socket
TOF-CHAR_C8_BR	AC Power / Charger (C8 electrical sockets) with Brazil socket
TOF-CHAR_TI	AC Power / Charger (electrical sockets Type I)

According to the annex IX of the European directive 93/42/EEC and its amendments, these above accessories are Class I rule 12.

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

According to the annex IX of the European directive 93/42/EEC and its amendments, this above accessory is Class I rule 1.

The declaration is based on following elements:

- Technical file DT_Tofscan & DT_WiTOF attesting the compliance to the essential requirements of the directive 93/42/EEC

Marseille, 21 December 2020

A handwritten signature in blue ink, appearing to be "F. BERNERT", written over a horizontal line.

Frederic BERNERT – President