

EC DECLARATION OF CONFORMITY

According to annexe V 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 device:

TOFSCAN, and its accessories

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 60601-2-10: 2012: Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

REFERENCE	DESCRIPTION
TOF	Complete ToFscan kit
TOF-U	Complete ToFscan with universal software version
TOF-MU	ToFscan NMT monitor
TOF-U-MU	ToFscan NMT monitor with universal software version
TOF-S2	Hand sensor and electrodes connector (length: 3 meters)
TOF-PS	Paediatric hand sensor and electrodes connector
TOF-FS	Foot sensor and electrodes connector
TOF-ES	Corrugator (eyebrow) sensor and electrodes connector (96 double-sided stickers included)
CAB-STIM3	Electric stimulation cable with electrodes connector only
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, the Product and its accessories are Class IIa rule 10.

The declaration is based on following elements:

-  Technical file DT_TOFSCAN attesting the compliance to the essential requirements of the directive 93/42/EEC
-  EC certificate n°35599, approval of full Quality Assurance System issued by the notified body n° 0459.

The CE mark applies starting from serial number 13-010 for TOF-MU and 2019-01 for TOF-U-MU.

Marseille, 2019/05/28



Frederic BERNERT – President