EC DECLARATION OF CONFORMITY

According to annexe II.3 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 devices:

WiTOF,
and its accessories

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 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
  - 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
  - IEC 62304 :2006 Medical device software - Software life-cycle processes
  - 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
WiTOF	Complete WiTOF kit
WiTOF-DEMO	Complete WiTOF kit for demonstration
WiTOF-MU	WiTOF NMT monitor
WiTOF-S	WiTOF Hand sensor
WiTOF-FS	WiTOF Foot sensor

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_WiTOF 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 2020-00001 for WiTOF-MU, 2020-00001 for WiTOF-S and 2020-00001 for WiTOF-ES.

Marseille, 05 August 2021

Frederic BERNERT – President