EC DECLARATION OF CONFORMITY

According to annexe II excluding section 4 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:

NEUROLIGHT, pupillometer

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
  - 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

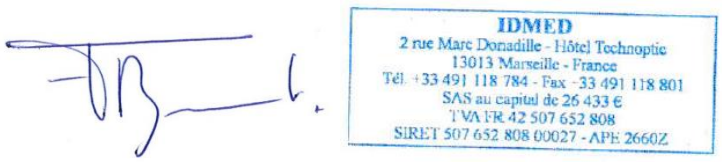
REFERENCE	DESCRIPTION
NL-2	NeuroLight kit
NL-MU	NeuroLight portable pupillometer

According to the annex IX of the European directive 93/42/EEC and its amendments, the Device and its accessories are Class IIa rule 10.

The declaration is based on following elements:

- Technical file DT_NeuroLight 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.

Marseille, 2020/11/03



Frederic BERNERT – President