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 NeuroLight (pupillometer) (Basic UDI-DI 36650230002LT & AlgiScan (pupillary algesimeter) (Basic UDI-DI 36650230003LV) 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

REFERENCE	IUD-DI	DESCRIPTION
STA-W2	3665023000429	Wireless charging station

According to the annex VIII of the Regulation (UE) 2017/745, this accessory is Class I rule 13.

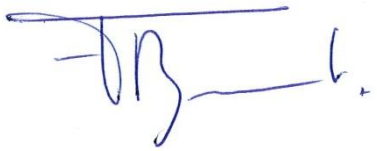
The Intended purpose of this accessory is to be used with the devices to monitor pupil size and reactivity or

to monitor the effects of certain anaesthetic products reaction thanks to the monitoring of the pupils following various stimuli, in a hospital or health establishment.

The declaration is based on following elements:

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

Marseille, 2022/04/05



Frederic BERNERT – President