



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) & AlgiScan (pupillary algesimeter) 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, these accessories are Class I rule 12.

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, 2021/05/26

A handwritten signature in blue ink, appearing to read "F. BERNERT".

Frederic BERNERT – President