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:

ALGISCAN, pupillometer
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

REFERENCE	DESCRIPTION
ALG	AlgiScan kit
ALG-MU	AlgiScan pupillary algesimeter
CAB-STIM3	Electric stimulation cable with electrodes connector only

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

Marseille, 2019/05/23

Frederic BERNERT – President