

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 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
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/Algiscan 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, 2019/05/23



Frederic BERNERT – President