EU Declaration of Conformity

Hereby we declare in exclusive responsibility that below identified product fully complies with the regulations of the Council Directive 93/42/EEC concerning medical devices (MDD) as amended by Directive 2007/47/EC. Conformity is assessed according the requirements of Annex II of the MDD.

nëo monitor

EEG/aEEG monitoring software
Product code: LE-800
Product version 1.2

The product is classified according to the MDD Annex IX as class IIa device,
GMDN code 35196, and meets the Essential Requirements of the MDD Annex I.

Product parts are marked with CE 0124

The Notified Body involved in the evaluation of the conformity is
DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart, Germany.

This declaration is valid until 2023-12-03.

Dated at Berlin, Germany, on the __18th___ day of ____February_____ 2021.

Frank Zanow

CEO
eemagine Medical Imaging Solutions GmbH
Gubener Straße 47
D-10243 Berlin
Germany