EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

eemagine Medical Imaging Solutions GmbH

Gubener Straße 47, 10243 Berlin, Germany

Certified location:

Gubener Straße 47, 10243 Berlin, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50850-Z5-00, the decision dated 2018-12-03 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-12-04 to 2023-12-03

Registration No.: 50850-16-05

DEKRA Certification GmbH • Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-12-03
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50850-16-05

Valid from 2018-12-04 to 2023-12-03

Revision status of the annex: 0 dated 2018-12-03

Devices/device categories included in the certificate:

Class II a:

- Software that is developed for EEG visualisation, archiving and analysis purposes: eemagine eeg
- EEG data acquisition system: eego, cognitrace, nëo monitor
- Neuronavigation software for Transcranial magnetic stimulation: visor2 software
- EEG data acquisition: eego amplifier

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-12-03
Notified Body ID-number: 0124