EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

eemagine Medical Imaging Solutions GmbH
Gubener Straße 47
10243 Berlin
Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000005560
Authorised Representative:	see Section 1
Limitations and Conditions:	see Section 2
List of Products, Risk Classification and Details:	see Section 3
Certificate History:	see Section 4

Certificate number:	44 911 222111	Valid from:	2025-06-13
Certification decision report No.:	3535 4289	Valid until:	2030-06-12
		First issued:	2025-06-13
		Issue date:	2025-06-13
		Edition:	1

Essen, 2025-06-13

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de
TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Certificate number: 44 911 222111

Section 1, Authorised Representative

Company name:	N/A
Street, No.:	--
Postal Code, City:	--
Country:	--

Section 2, Limitations and Conditions

The validity of this Certificate depends on:	The elimination of non-conformities according to the CAPA plan.
and the following conditions:	None
and / or is limited to the following:	N/A

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Section 3, List of Products, Risk Classification and Details

CLASS IIA

Category of device (MDx Code):	MDA 0203
	Active non-implantable devices for monitoring of vital physiological parameters
TD assessment report no.:	3536 6820
Basic UDI-DI:	++B195eegoamplifierZN
Devices or groups of devices	eego amplifier

Category of device (MDx Code):	MDA 0315
	Software
TD assessment report no.:	3535 4372
Basic UDI-DI:	++B195LE800UD
Devices or groups of devices	neo monitor
Basic UDI-DI:	++B195LE200TF
Devices or groups of devices	eego
Basic UDI-DI:	++B1956666016N
Devices or groups of devices	visor2

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Section 4, Certificate History

Edition	Date	Action leading to revision	Report reference
1	2025-06-13	Initial certification	3535 4289

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