

CERTIFICATE

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TÜV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

eemagine Medical Imaging Solutions GmbH
Gubener Strasse 47
10243 Berlin
Germany
[Facility ID: F004133]

with the locations according to Annex: n/a
with products according to Annex 1

operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for the following jurisdictions:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 excluding Part 1.6) – Full Quality Assurance Procedure.

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009.

Canada: Medical Devices Regulations – Part 1- SOR/98-282.

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable).

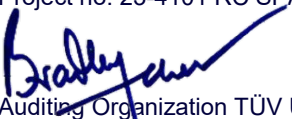
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Design, development, manufacture and distribution of EEG recorder, three-dimensional positioning system, and software for diagnostic purpose in psychiatry and neurology

Certificate Registration No. 24-1617-M
Project no. 23-4101 RC SPA

Valid from 2024-10-29
Valid until 2027-10-28
Initial Certification: 2020-01-09


Auditing Organization TÜV USA, Inc.

Salem, NH 2024-10-02, Edition 2



TÜV USA, Inc. is recognized under the Medical Device Single Audit Program

The validity of this certification document can be obtained by contacting the TÜV USA, Inc. office. Tel: 001-603-870-8023 (option 1), Email: medical-usa@tuv-nord.com

TÜV USA Inc.

215 Main Street

Salem, NH 03079

United States of America

tuv-nord.com/us

Annex 1

to Certificate Registration No. 24-1617-M

ISO 13485:2016 (MDSAP)

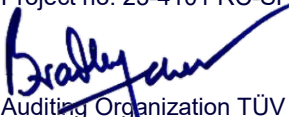
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Validity of Annex depends on the validity of the main certificate.

Products	UMDNS	GMDN
cognitrace	12-389, 17-413	47541
eego	12-389, 17-413	38736
eego amplifier	12-389, 17-413	36740
nëo monitor	12-597	38736
visor2	N/A	56641
waveguard	17-554	63131

End of List

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