ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 001232 0005 Rev. 00

Certificate Holder: **g.tec medical engineering GmbH**
Sierningstrasse 14
4521 Schiedlberg
AUSTRIA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Service of Biopotential Amplifiers for EEG, ECG, EOG and EMG Applications, Stimulation Devices for Neurological Diagnosis, Neuromuscular Stimulation Devices, Components and Software**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada,**
USA FDA, MHLW / PMDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **30-091-6041**

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(Arie Henkin)
Manager, Certification Body MHS
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Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

g.tec medical engineering GmbH
Sierningstrasse 14, 4521 Schiedlberg, AUSTRIA

g.tec medical engineering GmbH
Herbersteinstrasse 60, 8020 Graz, AUSTRIA

Facility Scopes:

g.tec medical engineering GmbH
Sierningstrasse 14, 4521 Schiedlberg, AUSTRIA

Design and Development, Production, Distribution and Service of Biopotential Amplifiers for EEG, ECG, EOG and EMG Applications, Stimulation Devices for Neurological Diagnosis, Neuromuscular Stimulation Devices, Components and Software
DUNS No: 30-091-6041

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Production, Delivery, Purchasing and End Controls of Biopotential Amplifiers For EEG, ECG, EOG and EMG Applications, Stimulation Devices for Neurological Diagnosis, Neuromuscular Stimulation Devices, Components and Software
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