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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 001232 0002 Rev. 02

Manufacturer:

g.tec medical engineering GmbH
Sierningstrasse 14
4521 Schiedlberg
AUSTRIA

Facility(ies):

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

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

Product Category(ies): **Active and passive stimulation devices for neurological diagnosis and therapy devices for neuromuscular stimulation devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164393

Valid from: 2020-01-28
Valid until: 2024-05-26

Date, 2020-01-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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