ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 07 01232 002

Manufacturer:

g.tec medical engineering GmbH
Sierningstrasse 14
4521 Schiedlberg
AUSTRIA

Facility(ies):

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

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

Product Category(ies):

stimulation devices for neurological diagnosis

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.: 713083880

Valid from: 2017-11-09
Valid until: 2022-11-08

Date, 2017-11-09

Stefan Preiß

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

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