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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 121276 0001 Rev. 00

Manufacturer:

Enterra Medical, Inc.
5353 Ste 400 Wayzata Blvd
Saint Louis Park MN 55416
USA

SRN Manufacturer - US-MF-000037677

Authorized Representative:

Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the 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 Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 121276 0001 Rev. 00

Report No.: 72195560

Valid from: 2024-07-22
Valid until: 2029-07-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-07-22

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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Classification:	Class III
Device Group:	J020803 - GASTRIC IMPLANTABLE NAUSEA THERAPY NEUROSTIMULATORS
Intended Purpose:	-
Classification:	Class III
Device Group:	J020804 - GASTRIC NEUROSTIMULATION LEADS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2024-07-22	72195560	Initial issuance

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