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 Technical Documentation Assessment Certificate (MDR)

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

No. G70 121276 0002 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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 121276 0002 Rev. 00

Report No.: 72196134

Valid from: 2024-06-21
Valid until: 2029-06-20

Issue date: 2024-06-21

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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Classification:	Class III
Device Group:	J020803 - GASTRIC IMPLANTABLE NAUSEA THERAPY NEUROSTIMULATORS
Basic UDI-DI:	085004596537800EH
Intended Purpose:	The implantable neurostimulator generates electrical pulses and delivers stimulation through two leads as part of a neurostimulation system for gastric electrical stimulation therapy.
Device(s):	Enterra™ II Neurostimulator Model 37800

Classification:	Class III
Device Group:	J020804 - GASTRIC NEUROSTIMULATION LEADS
Basic UDI-DI:	08500459654351M9
Intended Purpose:	The lead is an implanted component of a neurostimulator system intended to conduct electrical stimulation from a neurostimulator to the stomach muscle, as part of a neurostimulation system for gastric electrical stimulation therapy.
Device(s):	Enterra™ Unipolar Lead Kit Model 4351-35

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The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2024-06-21	72196134	- Initial issuance

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