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
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 012889 0044 Rev. 02

Manufacturer:
Zimmer MedizinSysteme GmbH
Junkersstr. 9
89231 Neu-Ulm
GERMANY

Facility(ies):
Zimmer MedizinSysteme GmbH
Junkersstr. 9, 89231 Neu-Ulm, GERMANY

Product Category(ies):
Devices for stimulation and inhibition, active rehabilitation devices, imaging devices utilising non-ionizing radiation, monitoring devices of non-vital physiological parameters, monitoring devices of vital physiological parameters, devices utilising non-ionizing radiation, non-active soft tissue implants

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.: 713164402

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

Date, 2020-01-28

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Dumitrovici Olga
Date: 2024.10.23 10:38:48 EEST
Reason: MoldSign Signature
Location: Moldova
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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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