Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 039709 1279 Rev. 00

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product Category(ies): **Tissue Heart Valves, Annuloplasty Rings and Bands and related Accessories for Surgical Implants, and Temporary Pacing Lead Systems**

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.: 72150078

Valid from: 2019-11-15
Valid until: 2024-05-26

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Kojevnikov Dmitrii
Date: 2024.05.21 16:12:56 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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 039709 1279 Rev. 00

Facility(ies):

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO

Medtronic Heart Valves Division
1941 Blair Avenue, Santa Ana CA 92705, USA

Medtronic Heart Valves Division
1851 E. Deere Avenue, Santa Ana, CA 92705, USA

Medtronic Fabrication S.A.S. Zone Industrielle SUD
Route D'Anor, 59610 Fourmies, FRANCE

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