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 041921 0035 Rev. 00

Manufacturer:

Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville FL 32216
USA

Product Category(ies):

Ventilation Tubes and Related Surgical Equipment; Middle Ear Prostheses; Disposable Sterile Surgical Instruments/Devices and Non-Sterile Surgical Instruments (With Suction); Surgical Drill Systems; Sinus Endoscopy Systems; Nerve Integrity Monitoring Systems; Nerve Stimulators; Rhinology, Laryngeal and Facial Implants; Endotracheal Tube Systems; Disposable Surgical Invasive Sponge Dressings, Packing's and Wipes; Bone Conduction Hearing System; including Fitting Software and magnetic 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.: 72149052

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

Date, 2020-05-05

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