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TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 041921 0034 Rev. 00

Manufacturer

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

Product Category(ies):

Sponge Dressings, Packing and Wipes, Class I Sterile Accessories for ENT, Head and Neck Applications

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72149051

Valid from: 2020-01-27
Valid until: 2024-05-26

Date, 2020-01-27

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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Facility(ies):

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

Medtronic Xomed, Inc.
950 Flanders Road, Mystic CT 06355, USA

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