



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 001537 0007 Rev. 00

Manufacturer:

Minnesota Medical Technologies Corporation

2446 Henry Road NW
Stewartville MN 55976
USA

SRN Manufacturer - US-MF-000008223

Authorized Representative:

MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 001537 0007 Rev. 00

Report No.: 72193365

Valid from: 2024-09-30

Valid until: 2029-09-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-30



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No. G10 001537 0007 Rev. 00

Classification: Class IIa
Device Group: G99 - GASTROINTESTINAL DEVICES - OTHER
Intended Purpose: Intended to assist adult patients and caregivers in the management of fecal incontinence

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

Revision History:

Rev.	Dated	Report	Description
00	2024-09-30	72193365	Initial issuance