European Declaration of Conformity

Fecal Incontinence Insert

APPLICABLE REF NUMBERS:

REF*	BRAND	DESCRIPTION
110104	MyMiracle	Rectal Insert, 30-pack, Standard
110106	MyMiracle	Rectal Insert, 30-pack, Large
110114	MyMiracle	Rectal Insert, Starter pack
69304	Navina	Rectal Insert, 30-pack, Standard
69305	Navina	Rectal Insert, 30-pack, Large
69306	Navina	Rectal Insert, Starter pack

* Generic article (model) number without the 2-digit suffix which may be specific for a region or country destination when distributing a Navina-brand article. Navina-brand articles may be provided to customers in boxes presented with different suffixes and UDIs.

REVISION HISTORY:

Rev	ECO	Date	Description of Change.	Author
1	140	6/5/2018	Implement into the Quality System.	R. Anglin
2	187	11/11/2019	Add field for SRN, add UDI and UMDNS codes, add intended purpose statement, add reference to EU common specifications, clarify conformity assessment procedure, add date for signature.	R. Anglin
3	232	16 October 2020	Add Navina trade name. Replace REF and UDI-DI (GTIN) numbers with Basic UDI-DI (GMN) number. Add list of REF numbers to title page. Remove company name from intended purpose statement.	R. Anglin
4	237	29 October 2020	Revised declaration statement per EC REP request.	R. Anglin
5	448	30 September 2024	Replaced MDD with EU MDR requirements. Update Intended purpose statement to be consistent with Tech File, IFU, and CER. Add MDR certificate number.	R. Anglin

Declaration of Conformity

REGU4201

In accordance with EU Medical Device Regulation 2017/745

Manufacturer	Minnesota Medical Technologies
Address	2446 Henry Road NW Stewartville, MN 55976, USA
Single Registration Number	US-MF-000008223
European Representative	MPS Medical Product Service GmbH
Address	Borngasse 20 35619 Braunfels, Germany
Single Registration Number	DE-AR-000005009

Product: Fecal Incontinence Insert

Trade Name(s)	Basic UDI - DI (GMN)	EMDN	Common Specification	CE Date
Navina, My Miracle	08654530003101LG	G99	Not applicable	2018-04-05

Intended Purpose

The Fecal Incontinence Insert is a recto anal insert which is intended to assist adult patients, 18 years and older, and caregivers in the management of fecal incontinence. The device is designed to help prevent the involuntary leakage of fecal matter through the anal canal.

The single use medical device is inserted via the anus into the anal canal and rectum. The device engages with and conforms to the anorectal junction and the anal canal to control the accidental leakage of fecal matter.

Classification

Class IIa

Regulation

This medical device is in conformity with Medical Device Regulation (MDR) 2017/745.

Notified Body

TÜV SÜD Product Service
GmbH Ridlerstraße 65
80339 München, Germany

Notified Body I.D. No.

0123

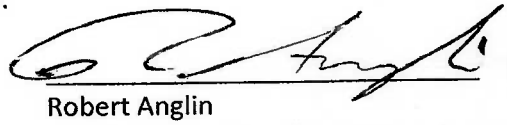
Conformity Assessment

MDR 2017/745, Article 52, paragraph 6.

Certificate

G10 001537 0007 Rev.00, Effective date 2024-09-30 through 2029-09-29.

I, the undersigned, hereby declare under my sole responsibility the medical device specified above meets the essential requirements and conforms to the Regulation listed herein, as certified by TÜV SÜD Product Service, Notified Body identification Number 0123.

Signature  Date 30 SEPTEMBER 2024

Robert Anglin
Vice President, Quality and Regulatory
Minnesota Medical Technologies
2446 Henry Road NW, Stewartville, MN 55976, USA

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
BS-MDR-099

Product Service

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

Product Service

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

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

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