European MDD to MDR Transition 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	350	4/13/2023	Implement into the Quality System	R. Anglin

Declaration of Conformity

REGU4201

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 Names	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 indicated for the management of Accidental Bowel Leakage (ABL) due to bowel incontinence. The rectal insert is designed for self-insertion to seal and help prevent the involuntary leakage of stool from the rectum.
Classification	Class IIa
Conformity Assessment	MDD Annex IX, invasive device, short term use, Rule 5, MDR 2017/745, Article 120(3), as amended by Regulation 2023/607.

Directives/Regulations:

- Medical Device Directive, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC. Conformity assessment route Annex II.
- Medical Device Regulation, 2017/745, Article 120(3) as amended by Regulation 2023-607 of 15 March 2023.

Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339, München, Germany
Notified Body I.D. No.	0123
Certificate	G1 17 08 01537 001, Effective date 2018-04-05 through 2023-04-04, extended per Regulation 2023/607 to 2028-12-31 .

The implementation of European Regulation 2017/745 has overwhelmed the capacity of notified bodies which are not sufficiently prepared to perform conformity assessment of medical devices to the Regulation. The European Commission therefore determined it necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directive 93/42/EEC and to extend the transitional period during which devices that are in conformity with this Directive can lawfully be placed on the market.

The European Commission has amended Regulation 2017/745 to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2024. This amendment provides legal certainty that Certificates issued by notified bodies for Class IIa devices in accordance with Directive 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall **remain valid after the end of the period indicated on the certificate until 31 December 2028**. The conditions of certificate validity listed within the amended Regulation are met:

- The device continues to comply with Directive 93/42/EEC,
- There are no significant changes in the design and intended purpose,
- The device does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health,
- No later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9),
- No later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

I, the undersigned, hereby declare under my sole responsibility the medical device specified above meets the requirements of Regulation 2017/745, Article 120(3) as amended by Regulation 2023/607 of 15 March 2023 and the Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC, as certified by TÜV SÜD Product Service, Notified Body identification Number 0123.

Signature: _____ Date: 17 APRIL 2023

Robert Anglin
Vice President, Quality & Regulatory
Minnesota Medical Technologies
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