Wellspect®

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - Navina Mini					1(3)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00098077	B	None	2024-01-24	Approved
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We,

Wellspect HealthCare
Aminogatan 1, P.O. Box 14,
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Sweden

being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of the Navina Mini device, including the products listed in the Annex I to this document, with the following characteristics:

- device class I, as determined by Rule 5, according to Regulation (EU) 2017/745, Annex VIII
- intended for Low-volume Transanal irrigation
- GMDN code: 45510
- EMDN category G / code(s): G020199 Gastrointestinal Lavage Tubes and Sets - Other
- Basic UDIDI/Global Model Number: 733338724104D3

Declare under our sole responsibility that the product(s) conform to the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council, on medical devices, and meet(s) the relevant General Safety and Performance Requirements of Annex I. All devices are designed, manufactured, tested and released for sale in accordance with the technical documentation according to Annex II and III of regulation (EU) 2017/745 and the applicable standards.

This declaration is approved and signed on the date on first page.

Wellspect HealthCare, Mölndal, Sweden

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TONI JORGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

ANNEX I

Article (model) No.*	Product Name, Description
69310	Navina Mini Start Set
69307	Navina Mini Set
69308	Navina Mini Extension Set

*Generic article number without the 2-digit suffix specific for a region or country destination when distributing an article.

REVISION HISTORY

Document Version	Change note/Description
B	New Basic UDI-DI assigned due to an error discovered in pervious Basic UDI-DI.