

EU DECLARATION OF CONFORMITY

DOC NAME						PAGES
EU Declaration of Conformity MDR - Navina Mini Cone						1(3)
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DC	00098078	B	None	2024-01-24	Approved	
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We,

Wellspect HealthCare
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being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of the Navina Mini Cone, 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: 46202
- EMDN category G / code(s):
 - o G020301 Rectal Tubes
- 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



TONI JØRGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

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ANNEX I

Article (model) No.*	Product Name, Description
69309	Navina Mini Refill Set

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

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REVISION HISTORY

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

