

## EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
Declaration of Conformity EU, Navina Mini					1(3)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00098077	A	None	2023-04-21	Approved
AUTHOR			APPROVED BY	CN/PROMO	
Gidlund, Sofia			Jørgensen, Toni Kennet	PR-83974	
VERIFIED BY				COPY NO	

Lundqvist, Johanna

We,

Wellspect HealthCare  
Aminogatan 1, P.O. Box 14,  
SE-431 21 Mölndal,  
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: 733333824104TG

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

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	00098077	A	2023-04-21	2 (3)

**ANNEX I**

<b>Article (model) No.*</b>	<b>Product Name, Description</b>
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.

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	00098077	A	2023-04-21	3 (3)

## REVISION HISTORY

Document Version	Change note/Description
A	First version