

## EU DECLARATION OF CONFORMITY

DOC NAME					PAGES	
EU Declaration of Conformity MDR - Navina Classic System					1(3)	
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE	
DC	10103	F	None	2025-01-16	Approved	
AUTHOR			APPROVED BY		CN/PROMO	
Ramzi, Emad			Ericson, Christina		PR-86383	
VERIFIED BY					COPY NO	
Raicevic, Andreas						

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 Classic Systems, 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 'Transanal irrigation'
- GMDN code: 45510
- EMDN category G/ code(s):
  - o 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 of Conformity is approved and signed as dated on first page.

Wellspect HealthCare, Mölndal, Sweden

CHRISTINA ERICSON  
VICE PRESIDENT QA IPS QARA WELLSPECT

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10103	F	2025-01-16	2 (3)

**ANNEX I**

<b>Article (model) No.*</b>	<b>Product Name, Description</b>
69005	Navina Classic System Regular
69006	Navina Classic System Regular Refill
69007	Navina Classic System Small
69008	Navina Classic System Small Refill
69017	Navina Classic System Cone
69018	Navina Classic System Cone Refill
69105	Navina Classic System
69106	Navina Classic System Refill

\*Generic article (model) number, without the 2-digit suffix which may be specific for a region or country's catalogue number and destination when distributing the article.

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10103	F	2025-01-16	3 (3)

Revision History

Document Version	Change note/Description
E	New Basic UDI-DI assigned due to an error in previous Basic UDI-DI identifier.
F	New Ref#: 69105 and 69106 for Navina Classic System and Classic System Refill, added to DoC.