

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	E	None	2023-12-19	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 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



TONI JØRGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

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ANNEX I

Article (model) No.*	Product Name, Description
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

*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.

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DC	10103	E	2023-12-19	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.