

EU DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
EU Declaration of Conformity MDR - Navina Consumable Set			1 (3)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10104-A	None	2022-11-08	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
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JLU11

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 System Consumable Set, including the products listed in the Annex I to this document, with the following characteristics:

- device class IIa, as determined by Rule 5, according to Regulation (EU) 2017/745, Annex VIII
- intended for Transanal irrigation
- GMDN code: 61094
- EMDN category G / code(s):
 - o G020102 Intestinal Lavage tubes and sets
- Basic UDIDI/Global Model Number: 0739253224108X7

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.

The conformity assessment procedure was performed following Annex IX of EU Regulation 2017/745.

DOC NO	DATE	PAGES
DC-10104-A	2022-11-08	2 (3)

This declaration is made based on the EU Technical Documentation Assessment Certificate MDR 780135 issued by the Notified Body:

BSI Group the Netherlands B.V. (2797)
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

This declaration of Conformity is approved and signed as dated on first page.

Wellspect HealthCare, Mölndal, Sweden



TONI JORGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

ANNEX I

Article (model) No.*	Product Name, Description
69003	Navina Consumable Set Regular
69004	Navina Consumable Set Small
69016	Navina Consumable Set Cone

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