

## EU DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
EU Declaration of Conformity MDR - Navina Rectal Catheter			1 (3)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10106-A	None	2022-11-08	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
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VERIFIERAD AV/VERIFIED BY			KOPIA NR/COPY NO

JLV11

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 Rectal Catheter, 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: 46202
- EMDN category G / code(s):
  - o G020301 Rectal Tubes
- 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.

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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



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TONI JORGENSEN  
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

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**ANNEX I**

<b>Article (model) No.*</b>	<b>Product Name, Description</b>
68940	Navina Catheter Set Regular
68943	Navina Catheter Set Small

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