

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES	
EU Declaration of Conformity MDR - Navina Rectal Catheter					1(4)	
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE	
DC	10106	B	None	2023-12-19	Approved	
AUTHOR			APPROVED BY		CN/PROMO	
Ramzi, Emad			Jørgensen, Toni		PR-84677	
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 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: 733338724106D7

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 TYPE	DOC NO	VERSION	DATE	PAGES
DC	10106	B	2023-12-19	2 (4)

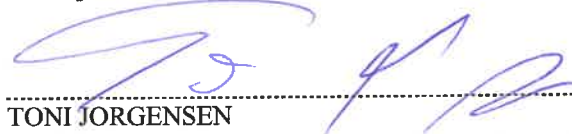
Wellspect®

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

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10106	B	2023-12-19	3 (4)

ANNEX I

Article (model) No.*	Product Name, Description
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.

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10106	B	2023-12-19	4 (4)

REVISION HISTORY

Document Version	Change note/Description
B	New Basic UDI-DI assigned due to an error in previous Basic UDI-DI identifier.