Wellspect®

EU DECLARATION OF CONFORMITY

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EU Declaration of Conformity MDR - Navina Smart System					1(4)
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DC	10108	C	Yes	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 Smart System, including the products listed in the Annex I to this document, with the following characteristics:

- device class IIa, as determined by Rule 12, according to Regulation (EU) 2017/745, Annex VIII
- intended for Transanal irrigation
- GMDN code: 60358
- EMDN category G / code(s):
  - G020199 Gastrointestinal Lavage, Tubes and Sets - Other
- Basic UDIDI/Global Model Number: 733338724105D5

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.

Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment, including required amendment 2015/863/EU Compliance for Category 8 (Medical devices and equipment) products (RoHS3 directive)

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment (RED directive)

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

Christina Ericson

CHRISTINA ERICSON
VICE PRESIDENT QA IPS QARA WELLSPECT

ANNEX I

Article (model) No.*	Product Name, Description
69009	Navina Smart System Regular
69010	Navina Smart System Small
69019	Navina Smart System Cone
69109	Navina Smart System

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

Revision History

Document Version	Change note/Description
B	New Basic UDI-DI assigned due to an error in previous Basic UDI-DI identifier.
C	New Ref#: 69109 Navina Smart System added to DoC.

Enclosure to MDR Declaration of conformity for Navina Smart System (DC-10108).

Conformity of Directive 2011/65/EU (*Annex I (Medical devices)*) of the European Parliament and of the Council of 8 June, 2011 and amendment 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment is presented in **RP-0013**.

Conformity of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment is presented in **EXT-R-0390**.