Wellspect®

EU DECLARATION OF CONFORMITY

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EU Declaration of Conformity MDR - Navina Accessories					1(3)
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We,

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being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of the Navina Accessory set, including the products listed in the Annex I to this document, with the following characteristics:

- device class I, as determined by Rule 1, according to Regulation (EU) 2017/745, Annex VIII
- intended for (optional) use with Navina System 'Transanal irrigation' devices
- GMDN code: 61651
- EMDN category G/ code(s):
  - G99 Gastrointestinal devices - other
- Basic UDIDI/Global Model Number: 733338724107D9

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 JORGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

ANNEX I

Article (model) No.*	Product Name, Description
69012	Navina Accessories

*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.

REVISION HISTORY

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