Wellspect®

EU DECLARATION OF CONFORMITY

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EU Declaration of Conformity MDR - Navina Tube Set					1(4)
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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 System Tube Set, including the products listed in the Annex I to this document, with the following characteristics:

- device class IIa, as determined by Rule 2, according to Regulation (EU) 2017/745, Annex VIII
- intended for Transanal irrigation
- GMDN code: 61094
- EMDN category G / code(s):
  - 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.

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
69011	Navina Tube Set

*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
C	GMDN code 46202 replaced by 61094, since 46202 is discontinued.