Wellspect®

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - hi-slip plus					1(5)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	10113	E	None	2026-09-29	Approved
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We,

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Sweden

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

- device class I(s), as determined by Rule 5, according to Regulation (EU) 2017/745, Annex VIII
- intended for intermittent urinary catheterization
- GMDN code: 45605
- EMDN category U / codes:
  - U01010501 Urological catheters, Nelaton self-lubricating
  - U01010601 Urological catheters, Tiemann self-lubricating
- Basic UDI-DI/Global Model Number: 733338724101CV

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.

Wellspect®

This declaration is made based on the Certificate of Conformity CE no. MDR 780135 R001 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
Vice President QARA

ANNEX I

Article (model) No.	Product Name, Description
TRHSPF1508A	hi-slip plus Nelaton Female 15 cm CH08
TRHSPF1510A	hi-slip plus Nelaton Female 15 cm CH10
TRHSPF1512A	hi-slip plus Nelaton Female 15 cm CH12
TRHSPF1514A	hi-slip plus Nelaton Female 15 cm CH14
TRHSPF1516A	hi-slip plus Nelaton Female 15 cm CH16
TRHSPF1518A	hi-slip plus Nelaton Female 15 cm CH18
TRHSPF2008A	hi-slip plus Nelaton Female/Paediatric 20 cm CH08
TRHSPF2010A	hi-slip plus Nelaton Female/Paediatric 20 cm CH10
TRHSPF2012A	hi-slip plus Nelaton Female 20 cm CH12
TRHSPF2014A	hi-slip plus Nelaton Female 20 cm CH14
TRHSPF2016A	hi-slip plus Nelaton Female 20 cm CH16
TRHSPF2018A	hi-slip plus Nelaton Female 20 cm CH18
TRHSPM4008A	hi-slip plus Nelaton Male 40 cm CH08
TRHSPM4010A	hi-slip plus Nelaton Male 40 cm CH10
TRHSPM4012A	hi-slip plus Nelaton Male 40 cm CH12
TRHSPM4014A	hi-slip plus Nelaton Male 40 cm CH14
TRHSPM4016A	hi-slip plus Nelaton Male 40 cm CH16
TRHSPM4018A	hi-slip plus Nelaton Male 40 cm CH18
TRHSPM4020A	hi-slip plus Nelaton Male 40 cm CH20
TRHSPM4022A	hi-slip plus Nelaton Male 40 cm CH22
TRHSPP2006A	hi-slip plus Nelaton Paediatric 20 cm CH06
TRHSPP3006A	hi-slip plus Nelaton Paediatric 30 cm CH06
TRHSPP3008A	hi-slip plus Nelaton Paediatric 30 cm CH08
TRHSPP3010A	hi-slip plus Nelaton Paediatric 30 cm CH10
TRHSPT4010A	hi-slip plus Tiemann Male 40 cm CH10
TRHSPT4012A	hi-slip plus Tiemann Male 40 cm CH12
TRHSPT4014A	hi-slip plus Tiemann Male 40 cm CH14
TRHSPT4016A	hi-slip plus Tiemann Male 40 cm CH16
TRHSPT4018A	hi-slip plus Tiemann Male 40 cm CH18
TRHSPT4020A	hi-slip plus Tiemann Male 40 cm CH20
TRHSPF1508B	hi-slip plus Nelaton Female 15 cm CH08
TRHSPF1510B	hi-slip plus Nelaton Female 15 cm CH10
TRHSPF1512B	hi-slip plus Nelaton Female 15 cm CH12
TRHSPF1514B	hi-slip plus Nelaton Female 15 cm CH14
TRHSPF1516B	hi-slip plus Nelaton Female 15 cm CH16
TRHSPF1518B	hi-slip plus Nelaton Female 15 cm CH18
TRHSPF2008B	hi-slip plus Nelaton Female/Paediatric 20 cm CH08
TRHSPF2010B	hi-slip plus Nelaton Female/Paediatric 20 cm CH10
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TRHSPF2018B	hi-slip plus Nelaton Female 20 cm CH18
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TRHSPM4010B	hi-slip plus Nelaton Male 40 cm CH10
TRHSPM4012B	hi-slip plus Nelaton Male 40 cm CH12
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TRHSPM4016B	hi-slip plus Nelaton Male 40 cm CH16
TRHSPM4018B	hi-slip plus Nelaton Male 40 cm CH18
TRHSPM4020B	hi-slip plus Nelaton Male 40 cm CH20
TRHSPM4022B	hi-slip plus Nelaton Male 40 cm CH22
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TRHSPT4018B	hi-slip plus Tiemann Male 40 cm CH18
TRHSPT4020B	hi-slip plus Tiemann Male 40 cm CH20

REVISION HISTORY

Document Version	Change note/Description
D	Added revision number for MDR certificate.
E	Updated EMDN term Updated revision number for MDR certificate Updated PRRC's name