Wellspect®

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric Insti-Cath					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	10112	E	None	2026-05-12	Approved
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We,

Wellspect HealthCare
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Sweden

being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of the LoFric Insti-Cath 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 bladder instillation therapy
- GMDN code: 34930
- EMDN category U / codes:
  - U01010501 Urological catheters, Nelaton self-lubricating
  - U01010601 Urological catheters, Tiemann self-lubricating
- Basic UDI-DI/Global Model Number: 733338724102CX

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 Certificate of Conformity CE No. 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
Vice President QARA

ANNEX I

Article (model) No.	Product Name, Description
40708*	LoFric Insti-Cath Nelaton Male 40 cm CH08
40710*	LoFric Insti-Cath Nelaton Male 40 cm CH10
40712*	LoFric Insti-Cath Nelaton Male 40 cm CH12
40714*	LoFric Insti-Cath Nelaton Male 40cm CH14
40808*	LoFric Insti-Cath Nelaton Female 20cm CH08
40810*	LoFric Insti-Cath Nelaton Female 20cm CH10
40812*	LoFric Insti-Cath Nelaton Female 20cm CH12
40814*	LoFric Insti-Cath Nelaton Female 20cm CH14
44008*	LoFric Insti-Cath Nelaton Paediatric 20cm CH08
44010*	LoFric Insti-Cath Nelaton Paediatric 20cm CH10
40912*	LoFric Insti-Cath Tiemann Male 40cm CH12

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

REVISION HISTORY

Document Version	Change note/Description
E	Updated to latest template and to current PRRCs name. Corrected in page 1 EMDN term description by changing from "Nelaton auto-lubricant" to "Nelaton self-lubricating" and from "Tiemann auto-lubricant" to "Tiemann self-lubricating". Corrected product name in the table in Annex 1 for 40708*/40710*/40712*/40714* by adding "Male", for 40808*/40810*/40812*/40814* by adding "Female" and for 44008*/44010* by moving "Paediatric" to be placed between "Nelaton" and "20cm".