

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	C	None	2022-11-08	Approved	
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We,

Wellspect HealthCare
 Aminogatan 1, P.O. Box 14,
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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 / code(s):
 - o U01010501 Urological catheters, Nelaton auto-lubricant
 - o U01010601 Urological catheters, Tiemann auto-lubricant
- Basic UDIDI/Global Model Number: 0739253224100WP

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.

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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



TONI JORGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

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ANNEX I

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

*Generic article number without the 2-digit suffix specific for a region or country destination when distributing an article. Articles are presented to customers in 10 or 30 pcs customer boxes, depending on product type

** Part of the presented 'product name, descriptions' may be in local language on local labels per local requirements for the identical article (model)]

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REVISION HISTORY

Document Version	Change note/Description
B	Updated with new SRN number.
C	Updated with new MDR certificate number.