

## EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	10111	E	None	2024-06-18	Approved
AUTHOR			APPROVED BY	CN/PROMO	
Skogbäck , Ulrika			Jørgensen, Toni	PR-85599	
VERIFIED BY				COPY NO	
Raicevic, Andreas					

We,

Wellspect HealthCare  
Aminogatan 1, P.O. Box 14,  
SE-431 21 Mölndal,  
Sweden

being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of the LoFric 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: 45603
- EMDN category U / codes:
  - o U01010501 Urological catheters, nelaton auto-lubricant
  - o U01010601 Urological catheters, tiemann auto-lubricant
- 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.


DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10111	E	2024-06-18	2 (4)

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

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10111	E	2024-06-18	3 (4)

## ANNEX I

Article (model) No.	Product Name, Description
40008*	LoFric Nelaton Male 40cm CH08
40010*	LoFric Nelaton Male 40cm CH10
40012*	LoFric Nelaton Male 40cm CH12
40014*	LoFric Nelaton Male 40cm CH14
40016*	LoFric Nelaton Male 40cm CH16
40018*	LoFric Nelaton Male 40cm CH18
40020*	LoFric Nelaton Male 40cm CH20
40022*	LoFric Nelaton Male 40cm CH22
40106*	LoFric Nelaton Paediatric 20cm CH06
40108*	LoFric Nelaton Paediatric 20cm CH08
40110*	LoFric Nelaton Paediatric 20cm CH10
40208*	LoFric Nelaton Paediatric 30cm CH08
40210*	LoFric Nelaton Paediatric 30cm CH10
40212*	LoFric Nelaton Paediatric 30cm CH12
40308*	LoFric Nelaton Female 20cm CH08
40310*	LoFric Nelaton Female 20cm CH10
40312*	LoFric Nelaton Female 20cm CH12
40314*	LoFric Nelaton Female 20cm CH14
40316*	LoFric Nelaton Female 20cm CH16
40318*	LoFric Nelaton Female 20cm CH18
40408*	LoFric Nelaton Female 15cm CH08
40410*	LoFric Nelaton Female 15cm CH10
40412*	LoFric Nelaton Female 15cm CH12
40414*	LoFric Nelaton Female 15cm CH14
40510*	LoFric Tiemann Male 40cm CH10
40512*	LoFric Tiemann Male 40cm CH12
40514*	LoFric Tiemann Male 40cm CH14
40516*	LoFric Tiemann Male 40cm CH16
40518*	LoFric Tiemann Male 40cm CH18

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

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	10111	E	2024-06-18	4 (4)

## REVISION HISTORY

Document Version	Change note/Description
E	Update related to CR-62807, New size of LoFric 30cm CH12. Added #40212, LoFric Nelaton Padiatric 30cm CH12 in Annex I