

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES	
EU Declaration of Conformity MDR - LoFric Dila-Cath					1(4)	
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE	
DC	10127	B	None	2024-02-08	Approved	
AUTHOR			APPROVED BY		CN/PROMO	
Lundqvist, Johanna			Jørgensen, Toni		PR-84964	
VERIFIED BY					COPY NO	
Lundqvist, Johanna						

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 Dila-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 dilatation of the urethra
- GMDN code: 32022
- EMDN category U / code: U03010201 Urethral Dilators
- Basic UDI-DI/Global Model Number: 733338724108DB

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	10127	B	2024-02-08	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	10127	B	2024-02-08	3 (4)

ANNEX I

Article (model) No.	Product Name, Description
40616*	LoFric Dila-Cath Nelaton 40cm CH16
40618*	LoFric Dila-Cath Nelaton 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	10127	B	2024-02-08	4 (4)

REVISION HISTORY

Document Version	Change note/Description
B	Moved to new template (PDM) and updated with new Basic UDI-DI code