Wellspect®

EU DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
EU Declaration of Conformity MDR - LoFric Dila-Cath			1 (3)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10127-A	None	2023-04-19	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
Gidlund, Sofia	Gidlund, Sofia	Jörgensen, Toni Kennet	
VERIFIERAD AV/VERIFIED BY		KOPIA NR/COPY NO	
JLU11			

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 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(s): U03010201 Urethral Dilators
- Basic UDIDI/Global Model Number: 733333824108TQ

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:

Wellspect®

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

ANNEX I

Article (model) No.*	Product Name, Description**
40616	LoFric Dila-Cath Nelaton 40cm CH16
40618	LoFric Dila-Cath Nelaton 40cm CH18

*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 30 pcs customer boxes.

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