

# EU DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
EU Declaration of Conformity MDR - LoFric Elle			1 (3)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10114-A	None	2023-04-04	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
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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 Elle 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: 64266
- EMDN category / code: U01010501 Urological catheters, Nelaton auto-lubricant
- Basic UDIDI/Global Model Number: 0739253224101WR

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:

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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**

<b>Article (model) No.*</b>	<b>Product Name, Description**</b>
41810XX*	LoFric Elle Nelaton 10 cm CH10
4181005	LoFric Elle Nelaton 10 cm CH10, 5-p
41812XX*	LoFric Elle Nelaton 10 cm CH12
4181205	LoFric Elle Nelaton 10 cm CH12, 5-p
41814XX*	LoFric Elle Nelaton 10 cm CH14
4181405	LoFric Elle Nelaton 10 cm CH14, 5-p

\*Generic article number without the 2-digit suffix specific for a region or country destination when distributing an article. Unless otherwise stated in table, articles are presented to customers in 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).