

# EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric Elle					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	10114	B	None	2024-02-07	Approved
AUTHOR			APPROVED BY	CN/PROMO	
Skogbäck , Ulrika			Jørgensen, Toni	PR-84738	
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 LoFric Elle product range, including the products listed in the Annex I to this document, with the following characteristics:

- device class Is, as determined by Rule 5, according to Regulation (EU) 2017/745, Annex VIII
- intended for intermittent urinary catheterization
- GMDN code: 64266
- EMDN category U / code: U01010501 Urological catheters, Nelaton 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	10114	B	2024-02-07	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	10114	B	2024-02-07	3 (4)

## ANNEX I

Article (model) No.	Product Name, Description
41810*	LoFric Elle Nelaton 10cm CH10
4181005	LoFric Elle Nelaton 10cm CH10, 5-pack
41812*	LoFric Elle Nelaton 10cm CH12
4181205	LoFric Elle Nelaton 10cm CH12, 5-pack
41814*	LoFric Elle Nelaton 10cm CH14
4181405	LoFric Elle Nelaton 10cm CH14, 5-pack

\*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	10114	B	2024-02-07	4 (4)

## REVISION HISTORY

Document Version	Change note/Description
B	Declaration of Conformity updated with new Basic UDI-DI code (CR-52094).