

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	D	None	2026-02-10	Approved
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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 self-lubricating
- 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.

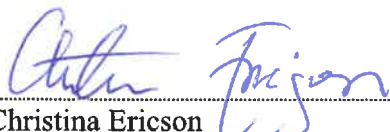
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This declaration is made based on the Certificate of Conformity CE No. MDR 780135 issued by the Notified Body:

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


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Christina Ericson
Vice President QA IPS and QARA Wellspect

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ANNEX I

Article (model) No.	Product Name, Description
41810*	LoFric Elle Nelaton Female 10cm CH10
4181005	LoFric Elle Nelaton Female 10cm CH10, 5-pack
41812*	LoFric Elle Nelaton Female 10cm CH12
4181205	LoFric Elle Nelaton Female 10cm CH12, 5-pack
41814*	LoFric Elle Nelaton Female 10cm CH14
4181405	LoFric Elle Nelaton Female 10cm CH14, 5-pack
41910*	LoFric Elle Pro CH10, Nelaton Female 10 cm
4191005	LoFric Elle Pro CH10, Nelaton Female 10 cm 5-pack
41912*	LoFric Elle Pro CH12, Nelaton Female 10 cm
4191205	LoFric Elle Pro CH12, Nelaton Female 10 cm 5-pack
41914*	LoFric Elle Pro CH14, Nelaton Female 10 cm
4191405	LoFric Elle Pro CH14, Nelaton Female 10 cm 5-pack

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

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DC	10114	D	2026-02-10	4 (4)

REVISION HISTORY

Document Version	Change note/Description
D	<p>New template</p> <p>Corrected in page 1 by changing from “Nelaton auto-lubricant” to “Nelaton self-lubricating”.</p> <p>Updated Annex I to include LoFric Elle Pro CH10, LoFric Elle Pro CH12 and LoFric Elle Pro CH14 (CR-63580).</p> <p>Corrected product name in Annex I for the LoFric Elle articles by adding the missing word “Female”.</p>