

EU DECLARATION OF CONFORMITY

DOC NAME						PAGES
EU Declaration of Conformity MDR - LoFric Origo						1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE	
DC	10100	F	None	2024-06-05	Approved	
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We,

Wellspect HealthCare
Aminogatan 1, P.O. Box 14,
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Sweden

being the Manufacturer, registered in the European Union under Single Registration Number (SRN) No. SE-MF-000026271, of LoFric Origo product ranges, 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: 45605
- EMDN category U / codes:
 - o U01010501 Urological catheters, Nelaton auto-lubricant (incl. Flexible tip)
 - o U01010601 Urological catheters, Tiemann 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.

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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



TONI JORGENSEN
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

ANNEX I

Article (model) No.	Product Name, Description
44208*	LoFric Origo Nelaton Paediatric 30cm CH08
4420805	LoFric Origo Nelaton Paediatric 30cm CH08, 5-pack
44210*	LoFric Origo Nelaton Paediatric 30cm CH10
4421005	LoFric Origo Nelaton Paediatric 30cm CH10, 5-pack
44212*	LoFric Origo Nelaton Paediatric 30cm CH12
4421205	LoFric Origo Nelaton Paediatric 30cm CH12, 5-pack
44310*	LoFric Origo Nelaton Male 40cm CH10
4431005	LoFric Origo Nelaton Male 40cm CH10, 5-pack
44312*	LoFric Origo Nelaton Male 40cm CH12
4431205	LoFric Origo Nelaton Male 40cm CH12, 5-pack
44314*	LoFric Origo Nelaton Male 40cm CH14
4431405	LoFric Origo Nelaton Male 40cm CH14, 5-pack
44316*	LoFric Origo Nelaton Male 40cm CH16
4431605	LoFric Origo Nelaton Male 40cm CH16, 5-pack
44318*	LoFric Origo Nelaton Male 40cm CH18
4431805	LoFric Origo Nelaton Male 40cm CH18, 5-pack
44410*	LoFric Origo Tiemann Male 40cm CH10
4441005	LoFric Origo Tiemann Male 40cm CH10, 5-pack
44412*	LoFric Origo Tiemann Male 40cm CH12
4441205	LoFric Origo Tiemann Male 40cm CH12, 5-pack
44414*	LoFric Origo Tiemann Male 40cm CH14
4441405	LoFric Origo Tiemann Male 40cm CH14, 5-pack
44416*	LoFric Origo Tiemann Male 40cm CH16
4441605	LoFric Origo Tiemann Male 40cm CH16, 5-pack
44418*	LoFric Origo Tiemann Male 40cm CH18
4441805	LoFric Origo Tiemann Male 40cm CH18, 5-pack
44512*	LoFric Origo Flexible Male 40cm CH12
4451205	LoFric Origo Flexible Male 40cm CH12, 5-pack
44514*	LoFric Origo Flexible Male 40cm CH14
4451405	LoFric Origo Flexible Male 40cm CH14, 5-pack
44612*	LoFric Origo Sleeve Nelaton Male 40cm CH12
4461205	LoFric Origo Sleeve Nelaton Male 40cm CH12, 5-pack
44614*	LoFric Origo Sleeve Nelaton Male 40cm CH14
4461405	LoFric Origo Sleeve Nelaton Male 40cm CH14, 5-pack
44616*	LoFric Origo Sleeve Nelaton Male 40cm CH16
4461605	LoFric Origo Sleeve Nelaton Male 40cm CH16, 5-pack
44812*	LoFric Origo Sleeve Flexible Male 40 cm CH12
4481205	LoFric Origo Sleeve Flexible Male 40 cm CH12, 5-pack
44814*	LoFric Origo Sleeve Flexible Male 40 cm CH14
4481405	LoFric Origo Sleeve Flexible Male 40 cm CH14, 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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REVISION HISTORY

Document Version	Change note/Description
F	Update related to CR 62814: Added LoFric Origo Sleeve Flexible articles 44812 and 44814, including 5-pack. Added clarification that code U01010501 is also including Flexible tip.