

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	D	None	2024-02-07	Approved	
AUTHOR			APPROVED BY		CN/PROMO	
Skogbäck , Ulrika			Jørgensen, Toni		PR-84874	
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 Origo 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: 45605
- EMDN category U / codes:
 - o U01010501 Urological catheters, Nelaton auto-lubricant
 - 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.

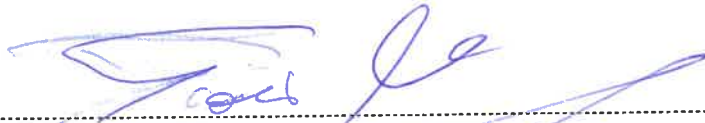
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This declaration is made based on the Certificate of Conformity CE No. MDR 780135 issued by the Notified Body:

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

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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

* 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
D	<p>Declaration of Conformity updated with new Basic UDI-DI code (CR-50294).</p> <p>Added article No for 5-pack for LoFric Origo.</p> <p>Added LoFric Origo Flexible Male (#44512 and #44514) moved from DC-00097888:A and additional article No for 5-pack of LoFric Origo Flexible.</p> <p>LoFric Sense assortment moved to DC-00108648</p> <p>LoFric Primo assortment moved to DC-00108647</p> <p>LoFric Hydro-Kit assortment moved to DC-00108646</p>