

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
Declaration of Conformity EU, LoFric Origo Flexible					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00097888	A	None	2023-02-07	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 the LoFric Origo 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: 45605
- EMDN category / code(s):
 - o U01010501 Urological catheters, Nelaton auto-lubricant
- Basic UDIDI/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	00097888	A	2023-02-07	2 (4)

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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

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	00097888	A	2023-02-07	3 (4)

ANNEX I

Article No.*	Product Name, Description**
44512	LoFric Origo Flexible Male 40 cm CH12
44514	LoFric Origo Flexible Male 40 cm CH14

*Generic article number without the 2-digit suffix specific for a region or country destination when distributing an article. Articles are presented to customers in 5 or 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)

DOC TYPE	DOC NO	VERSION	DATE	PAGES
DC	00097888	A	2023-02-07	4 (4)

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REVISION HISTORY

Document Version	Change note/Description
A	New DoC for Origo Flexible tip with new Basic UDIDI