

EU DECLARATION OF CONFORMITY

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| DOC NAME | | | | | PAGES | |
| EU Declaration of Conformity MDR - LoFric Origo | | | | | 1(4) | |
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| DC | 10100 | E | None | 2024-05-08 | 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 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
 - 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 |
| 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 |

*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 |
|------------------|--|
| E | Update due to project Fusion (CR-50951). Added LoFric Origo Sleeve Nelaton articles 44612, 44614, 44616 including 5-pack. |