

EU DECLARATION OF CONFORMITY

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| DOC NAME | | | | | PAGES |
| EU Declaration of Conformity MDR - LoFric | | | | | 1(4) |
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| AUTHOR | | | APPROVED BY | CN/PROMO | |
| Lundqvist, Johanna | | | Jørgensen, Toni | PR-84658 | |
| VERIFIED BY | | | | COPY NO | |
| Raicevic, Andreas | | | | | |

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 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: 45603
- 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

ANNEX I

| Article (model) No. | Product Name, Description |
|---------------------|-------------------------------------|
| 40008* | LoFric Nelaton Male 40cm CH08 |
| 40010* | LoFric Nelaton Male 40cm CH10 |
| 40012* | LoFric Nelaton Male 40cm CH12 |
| 40014* | LoFric Nelaton Male 40cm CH14 |
| 40016* | LoFric Nelaton Male 40cm CH16 |
| 40018* | LoFric Nelaton Male 40cm CH18 |
| 40020* | LoFric Nelaton Male 40cm CH20 |
| 40022* | LoFric Nelaton Male 40cm CH22 |
| 40106* | LoFric Nelaton Paediatric 20cm CH06 |
| 40108* | LoFric Nelaton Paediatric 20cm CH08 |
| 40110* | LoFric Nelaton Paediatric 20cm CH10 |
| 40208* | LoFric Nelaton Paediatric 30cm CH08 |
| 40210* | LoFric Nelaton Paediatric 30cm CH10 |
| 40308* | LoFric Nelaton Female 20cm CH08 |
| 40310* | LoFric Nelaton Female 20cm CH10 |
| 40312* | LoFric Nelaton Female 20cm CH12 |
| 40314* | LoFric Nelaton Female 20cm CH14 |
| 40316* | LoFric Nelaton Female 20cm CH16 |
| 40318* | LoFric Nelaton Female 20cm CH18 |
| 40408* | LoFric Nelaton Female 15cm CH08 |
| 40410* | LoFric Nelaton Female 15cm CH10 |
| 40412* | LoFric Nelaton Female 15cm CH12 |
| 40414* | LoFric Nelaton Female 15cm CH14 |
| 40510* | LoFric Tiemann Male 40cm CH10 |
| 40512* | LoFric Tiemann Male 40cm CH12 |
| 40514* | LoFric Tiemann Male 40cm CH14 |
| 40516* | LoFric Tiemann Male 40cm CH16 |
| 40518* | LoFric Tiemann Male 40cm CH18 |

*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 | Moved to new template (PDM) and updated with new Basic UDI-DI code. |