

EU DECLARATION OF CONFORMITY

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| DOC NAME | | | | | | PAGES |
| EU Declaration of Conformity MDR - LoFric Elle | | | | | | 1(4) |
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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 Elle 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: 64266
- EMDN category U / code: U01010501 Urological catheters, Nelaton 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.

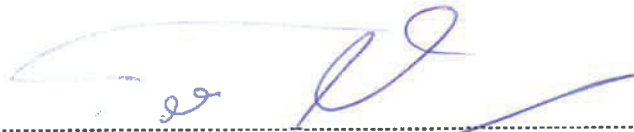
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This declaration is made based on the Certificate of Conformity CE No. MDR 780135 issued by the Notified Body:

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 |
|---------------------|---------------------------------------|
| 41810* | LoFric Elle Nelaton 10cm CH10 |
| 4181005 | LoFric Elle Nelaton 10cm CH10, 5-pack |
| 41812* | LoFric Elle Nelaton 10cm CH12 |
| 4181205 | LoFric Elle Nelaton 10cm CH12, 5-pack |
| 41814* | LoFric Elle Nelaton 10cm CH14 |
| 4181405 | LoFric Elle Nelaton 10cm 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 |
|------------------|--|
| C | New version due to expanded patient population to include adolescent and children (CR-62578) |