

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR LoFric Primo, Sense, H-K, Origo					1(5)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	10100	C	None	2022-11-08	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 the LoFric Primo, LoFric Sense, LoFric Hydro-Kit and LoFric Origo product ranges, 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
 - o U01010601 Urological catheters, Tiemann auto-lubricant
- Basic UDIDI/Global Model Number: 0739253224101WR

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.

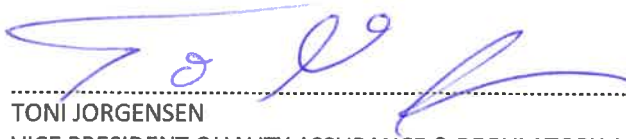
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This declaration is made based on the Certificate of Conformity CE No. MDR 780135 issued by the Notified Body:

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 No.*	Product Name, Description**
41008	LoFric Primo Nelaton Male 40cm CH08
41010	LoFric Primo Nelaton Male 40cm CH10
41012	LoFric Primo Nelaton Male 40cm CH12
41014	LoFric Primo Nelaton Male 40cm CH14
41016	LoFric Primo Nelaton Male 40cm CH16
41018	LoFric Primo Nelaton Male 40cm CH18
41106	LoFric Primo Nelaton Paediatric 20cm CH06
41108	LoFric Primo Nelaton Paediatric 20cm CH08
41110	LoFric Primo Nelaton Paediatric 20cm CH10
41308	LoFric Primo Nelaton Female 20cm CH08
41310	LoFric Primo Nelaton Female 20cm CH10
41312	LoFric Primo Nelaton Female 20cm CH12
41314	LoFric Primo Nelaton Female 20cm CH14
41316	LoFric Primo Nelaton Female 20cm CH16
41318	LoFric Primo Nelaton Female 20cm CH18
41408	LoFric Primo Nelaton Female 15cm CH08
41410	LoFric Primo Nelaton Female 15cm CH10
41412	LoFric Primo Nelaton Female 15cm CH12
41414	LoFric Primo Nelaton Female 15cm CH14
41510	LoFric Primo Tiemann Male 40cm CH10
41512	LoFric Primo Tiemann Male 40cm CH12
41514	LoFric Primo Tiemann Male 40cm CH14
41516	LoFric Primo Tiemann Male 40cm CH16
41518	LoFric Primo Tiemann Male 40cm CH18
41608	LoFric Sense Nelaton Female 15cm CH08
41610	LoFric Sense Nelaton Female 15cm CH10
41612	LoFric Sense Nelaton Female 15cm CH12
41614	LoFric Sense Nelaton Female 15cm CH14
42008	LoFric Hydro-Kit Nelaton Male 40cm CH08
42010	LoFric Hydro-Kit Nelaton Male 40cm CH10
42012	LoFric Hydro-Kit Nelaton Male 40cm CH12
42014	LoFric Hydro-Kit Nelaton Male 40cm CH14
42016	LoFric Hydro-Kit Nelaton Male 40cm CH16
42018	LoFric Hydro-Kit Nelaton Male 40cm CH18
42108	LoFric Hydro-Kit Nelaton Paediatric 20cm CH08
42110	LoFric Hydro-Kit Nelaton Paediatric 20cm CH10
42308	LoFric Hydro-Kit Nelaton Female 20cm CH08
42310	LoFric Hydro-Kit Nelaton Female 20cm CH10
42312	LoFric Hydro-Kit Nelaton Female 20cm CH12
42314	LoFric Hydro-Kit Nelaton Female 20cm CH14
42316	LoFric Hydro-Kit Nelaton Female 20cm CH16
42318	LoFric Hydro-Kit Nelaton Female 20cm CH18
42510	LoFric Hydro-Kit Tiemann Male 40cm CH10
42512	LoFric Hydro-Kit Tiemann Male 40cm CH12
42514	LoFric Hydro-Kit Tiemann Male 40cm CH14

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Article No.*	Product Name, Description**
42516	LoFric Hydro-Kit Tiemann Male 40cm CH16
42518	LoFric Hydro-Kit Tiemann Male 40cm CH18
44208	LoFric Origo, Nelaton Paediatric 30cm CH08
44210	LoFric Origo, Nelaton Paediatric 30cm CH10
44212	LoFric Origo, Nelaton Paediatric 30cm CH12
44310	LoFric Origo, Nelaton Male 40cm CH10
44312	LoFric Origo, Nelaton Male 40cm CH12
44314	LoFric Origo, Nelaton Male 40cm CH14
44316	LoFric Origo, Nelaton Male 40cm CH16
44318	LoFric Origo, Nelaton Male 40cm CH18
44410	LoFric Origo, Tiemann Male 40cm CH10
44412	LoFric Origo, Tiemann Male 40cm CH12
44414	LoFric Origo, Tiemann Male 40cm CH14
44416	LoFric Origo, Tiemann Male 40cm CH16
44418	LoFric Origo, Tiemann Male 40cm CH18

*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)

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REVISION HISTORY

Document Version	Change note/Description
C	Updated with new CE No. MDR 780135

