

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric Hydro-Kit					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00108646	A	None	2024-02-13	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 Hydro-Kit 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 U / code(s):
 - 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
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 CH010
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
42516*	LoFric Hydro-Kit Tiemann Male 40cm CH16
42518*	LoFric Hydro-Kit Tiemann Male 40cm CH18
42008**3	LoFric Hydro-Kit Nelaton Male 40cm CH08
42010**3	LoFric Hydro-Kit Nelaton Male 40cm CH10
42012**3	LoFric Hydro-Kit Nelaton Male 40cm CH12
42014**3	LoFric Hydro-Kit Nelaton Male 40cm CH14
42016**3	LoFric Hydro-Kit Nelaton Male 40cm CH16
42018**3	LoFric Hydro-Kit Nelaton Male 40cm CH18
42108**3	LoFric Hydro-Kit Nelaton Paediatric 20cm CH08
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42318**3	LoFric Hydro-Kit Nelaton Female 20cm CH18
42510**3	LoFric Hydro-Kit Tiemann Male 40cm CH10
42512**3	LoFric Hydro-Kit Tiemann Male 40cm CH12
42514**3	LoFric Hydro-Kit Tiemann Male 40cm CH14
42516**3	LoFric Hydro-Kit Tiemann Male 40cm CH16
42518**3	LoFric Hydro-Kit Tiemann Male 40cm CH18

*Article (model) number 20-pack without the 2-digit suffix specific for a region or country destination when distributing an article.

** Article (model) number without the 2-digit suffix specific for a region or country destination when distributing an article, where 3 is representing 30-pack.

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REVISION HISTORY

Document Version	Change note/Description
A	<p>New Doc.id for Declaration of Conformity for LoFric Hydro-Kit.</p> <p>LoFric Hydro-Kit assortment removed from DC-10100:C</p> <p>New Basic UDI-DI code (CR-50294)</p> <p>DoC contain Article No's for both 20- and 30-pack</p>