Wellspect®

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric Primo					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00108647	B	None	2026-05-20	Approved
AUTHOR		APPROVED BY			CN/PROMO
Lundqvist, Johanna		Ericson, Christina			PR-88987
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 LoFric Primo 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):
  - U01010501 Urological catheters, Nelaton self-lubricating
  - U01010601 Urological catheters, Tiemann self-lubricating
- 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.

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

Christina Ericson
Vice President QARA

ANNEX I

Article (model) 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

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

REVISION HISTORY

Document Version	Change note/Description
A	New doc.id for Declaration of Conformity for LoFric Primo. LoFric Primo assortment removed from DC-10100:C New Basic UDI-DI code (CR-50294)
B	Updated to latest template and to current PRRCs name.