Wellspect®

EU DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
EU Declaration of Conformity MDR LoFric			1 (3)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10111-B	None	2022-08-12	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
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JLU11

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 / code(s):
  - U01010501 Urological catheters, Nelaton auto-lubricant
  - 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.

This declaration is made based on the Certificate of Conformity CE No. MDR 749583 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 2022-08-12

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

*Generic article (model) number *without* the 2- or 3-digit suffix, which together with the model number builds the local Catalogue number (covered by the declaration) and may be specific for a region or country destination when distributing an article. Articles are presented to users in 30 pcs customer boxes.

** Part of the presented 'product name, descriptions' may be in local language on local labels per local requirements for the identical generic article (model)