

EU DECLARATION OF CONFORMITY

DOC NAME					PAGES
EU Declaration of Conformity MDR - LoFric Sense					1(4)
DOC TYPE	DOC NO	VERSION	ENCLOSURE	DATE	STATE
DC	00108648	A	None	2024-02-15	Approved
AUTHOR		APPROVED BY		CN/PROMO	
Skogbäck , Ulrika		Jørgensen, Toni		PR-84972	
VERIFIED BY				COPY NO	
Lundqvist, Johanna					

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 Sense 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
- 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
41608*	LoFric Sense Nelaton Female 15cm CH08
4160805	LoFric Sense Nelaton Female 15cm CH08, 5-pack
41610*	LoFric Sense Nelaton Female 15cm CH10
4161005	LoFric Sense Nelaton Female 15cm CH10, 5-pack
41612*	LoFric Sense Nelaton Female 15cm CH12
4161205	LoFric Sense Nelaton Female 15cm CH12, 5-pack
41614*	LoFric Sense Nelaton Female 15cm CH14
4161405	LoFric Sense Nelaton Female 15cm 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
A	New doc.id for Declaration of Conformity for LoFric Sense. LoFric Sense assortment removed from DC-10100:C New Basic UDI-DI code (CR-50294) Added article No for 5-pack for LoFric Sense.