

# DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
LoFric Ready to Use Urinary Catheters			1 (2)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10101-C	None	2020-05-11	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
Ramzi, Emad	Ramzi, Emad	Fahlström, Herman	

Declaration of conformity in accordance with the following Laws and Directives:

The Act (1993:584) Medical Devices, LVFS 2003:11 and the Directive on Medical Devices (93/42/EEC).

BRAND NAME OR TRADE MARK

LoFric Elle

CLASS OF DEVICE ACCORDING TO ANNEX IX IN 93/42/EEC

Class I Sterile (s)

APPLICABLE RULE ACCORDING TO ANNEX IX IN 93/42/EEC

Rule 5: Invasive devices with respect to body orifices intended for transient use

ARTICLE NUMBER(S)

ARTICLE NUMBER	DESCRIPTION
41810xx*	LoFric Elle Nelaton 10cm CH10
4181005	LoFric Elle Nelaton 10cm CH10, 5-p
41812xx*	LoFric Elle Nelaton 10cm CH12
4181205	LoFric Elle Nelaton 10cm CH12, 5-p
41814xx*	LoFric Elle Nelaton 10cm CH14
4181405	LoFric Elle Nelaton 10cm CH14, 5-p

\*Generic article numbers without the two-digit suffix specific for a region or country destination when distributing an article. Unless otherwise stated in table, the articles are presented to customers in 30 pcs customer box.

CONFORMITY ASSESSMENT ROUTE ACCORDING TO 93/42/EEC ANNEX V, VII

New Notified Body: BSI Group the Netherlands B.V. (2797), Certificate No. CE 588583

As the manufacturer/distributor within the European Economic Area, we declare under our sole responsibility that the product(s) listed are in conformance with the provisions of the directives and the national laws stated above.

Wellspect HealthCare, Mölndal



HERMAN FAHLSTRÖM  
VICE PRESIDENT QUALITY ASSURANCE & REGULATORY AFFAIRS

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HEALTHCARE

DOC NO	DATE	PAGES
DC-10101-C	2020-05-11	2 (2)

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