DECLARATION OF CONFORMITY

DESCRIPTION			PAGES
LoFric DilaCath (POBE)			1 (1)
DOC NO	ENCLOSURE	DATE	STATUS
DC-10056-C	None	2020-02-27	Approved
PREPARED BY	ISSUED BY	APPROVED BY	
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VERIFIERAD AV/VERIFIED BY		KOPIA NR/COPY NO	

SEAOL11

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 Dila-Cath

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
40616	LoFric Dila-Cath Nelaton 40cm CH16
40618	LoFric Dila-Cath Nelaton 40cm CH18

*Generic article number without the two digit suffix specific for a region or country destination when distributing an article

CONFORMITY ASSESSMENT ROUTE ACCORDING TO 93/42/EEC
ANNEX V, VII
ANNEX V, Old Notified Body: BSI Assurance UK Ltd (0086),
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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