SPECIFICATION

DESCRIPTION			PAGES
Technical Product Data Sheet - LoFric Classic POBE			1 (6)
DOC NO	ENCLOSURE	DATE	STATUS
PB-MH-0001-C	None	2012-11-14	Approved
PREPARED BY	ISSUED BY		APPROVED BY
Walfridsson, Karin	Walfridsson, Karin		Ewert, Christian

TECHNICAL PRODUCT DATA SHEET
LOFRIC CLASSIC (POBE)

Contents

Supplier details

Supplier name	Wellspect HealthCare, a division of DENTSPLY IH AB
Address	Aminogatan 1, P.O. Box 14, SE-431 21 Mölndal, Sweden
Phone no.	Phone: +46 31 376 40 00

Product

Product trade mark or trade name	LoFric
Reference no.	40008xx, 40010xx, 40012xx, 40014xx, 40016xx, 40018xx, 40020xx, 40022xx 40106xx, 40108xx, 40110xx 40206xx, 40208xx, 40210xx 40308xx, 40310xx, 40312xx, 40314xx, 40316xx, 40318xx 40406xx, 40408xx, 40410xx, 40412xx, 40414xx (40416xx, 40418xx) 40510xx, 40512xx, 40514xx, 40516xx, 40518xx, 40520xx
Description	Single use urinary catheter
Country of origin	Sweden
Intended use of the product	The LoFric single use urinary catheter is intended for intermittent urinary catheterisation
Does the device need to be used in combination with other devices, adapters or other accessories?	No
Is the product a medical device?	Yes
Is the device an implant?	No
Classification according to MDD 93/42/EEC?	☐ I ☒ I, sterile ☐ IIa ☐ IIb ☐ III

Classification rule?	Rule no. 5
Are handling instructions provided with the device?	Yes, on the carton (Customer box)
GMDN Code	36125 (Catheter, urological, intermittent)

Materials

Catheter (incl. connector) material	Polyolefin-based elastomer (POBE)
Coating material	Polyvinyl pyrrolidone (PVP), sodium chloride (NaCl)
Item package material	Lacquered paper, laminated film of polypropylene (PP) and polyethylene (PE)

Product composition (physical, chemical and biological properties of the product)

Toxicity	Non toxic
Flammability	Not applicable
Bio compatibility	Bio compatible in accordance with ISO 10993

Generic materials of construction:

Does this product contain silicon rubber?	No
Does this product contain silicon lubricant?	No
Does this product contain latex?	No*
Does the packaging contain latex?	No*
Does this product contain PVC?	No
If yes, which parts are PVC?	-
Does this product or its packaging contain polystyrene?	No
Does this product contain any substances present in the candidate list for authorisation according to REACH? **→ If yes; name of the substance?** **→ If yes; does the product labelling give the name of the substance?**	No - -
Does this product contain DEHP Di(2-ethylhexyl) phthalate?	No

* See also Latex Statement

Packaging and storage

Mode of delivery:	Individual packaging 30 catheters per carton (Customer box) 4 cartons per transport box
Is the product double wrapped?	No, it is a single sterile barrier
Does the device have to remain in its primary packaging?	Yes
Are storage instructions provided with the device?	Yes, on the carton (Customer box)
Are there any specific instructions for storage?	Yes, dry place at room temperature
Is the product expiration dated?	Yes
Shelf life:	3,5 years
Is the expiration date relative to the packaging and/or the product degradation?	The product (catheter and item package) is validated for the expiration time.

Packaging components (item package / carton / transport box):

- Cardboard:	No / Yes / Yes
- Paper:	Yes / No / No
- Glass:	No / No / No
- Metal:	No / Yes (Al-foil 9 µm) / No
- Latex:	No / No / No*
- Cotton:	No / No / No
- Organic:	No / No / No
- Plastic (type of plastic):	Polyethylene (PE), polypropylene (PP) / polyethylene terephtalate (PETP), linear low-density polyethylene (LLDPE) / No
- Other:	-

* See also Latex Statement

Regulatory information

Is the product classed as a Medical Device as per the directive 93/42/EEC?	Yes
MDD Class:	Class I, Sterile
Applicable classifications rules:	Rule no. 5
Notified Body name and no.:	BSI 0086
CE certificate no.:	CE 588583

Are there any necessary instructions for use (IFU) supplied with the products?	Yes, IFU on the carton (Customer box)

List of applicable international standards / vertical norms related to the product:	ISO 10993, EN 1616, ISO 11607, ISO 11135, ISO 14971, EN 13868
List of accessories, adapters and other devices or equipments which are intended to be used in combination with the product:	None Can be attached to standard urine collection bags
Is the manufacturing facility for this component ISO / EN approved?	BS EN ISO 9001 / BS EN ISO 13485

Sterilisation

Method of sterilisation:	Gas: Ethylene Oxide
Can the product be resterilised?	No, re-sterilisation not allowed
Why can it not be resterilised?	LoFric is a single use product. Once used the unique surface coating has deteriorated and the catheter is no longer sterile. Re-use may cause higher friction, discomfort, bleeding, urinary tract infections and in the long-term strictures and epididymitis.

Category as defined in EN ISO 10993-1:

Nature of body contact:	Surface contact
Duration of contact:	Limited exposure (cumulative effect evaluated)

Product contamination control

Is the product produced in a controlled manufacturing environment which complies with ISO13485?	Yes
Do the products require a non-pyrogenic claim?	No

Human/animal origin

Does the product contain any materials of human origin?	No
Does the product contain any materials of animal origin?	No
Does the product come into contact with material of animal origin during the manufacturing process?	No

Environmental section

Does the product or products packaging (ink, labels, banding, packing material etc.) contain heavy metals e.g. Pb, Hg, Cd, Cr in such a way that the combined totals exceed 100ppm? (European directive 94/62/EEC)	No

Does the product contain, or is manufactured or sterilised with ozone depleting agents: - **CFC's (Freon, Halon, Carbon Tetrachloride, Methyl Chloroform):** - **HCFC's:**	 No No
Chlorine bleached materials (product / packaging):	No / No
Recycled materials (product / packaging):	No / Yes

Does a recognised environmental label exist for the product area?	No
Does the product carry an environmental label?	No
Is the device tested for bioburden as a part of your quality system?	Yes
Can the product and its packaging be recycled?	See below

Waste handling

Recommendations for waste handling (incineration / landfill / recycling):

Product (catheter):	Incineration
Item package:	Incineration
Carton (Customer box):	Recycling
Transport box:	Recycling
Aluminium bag	Recycling

Recycling label:

Product (catheter):	No
Item package:	No
Carton (Customer box):	Yes
Transport box:	Yes