USER NEEDS SPECIFICATION

DESCRIPTION			PAGES
Technical Product Data Sheet - LoFric Hydro-Kit POBE			1 (6)
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PREPARED BY	ISSUED BY		APPROVED BY
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TECHNICAL PRODUCT DATA SHEET
LOFRIC HYDRO-KIT (POBE)

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1 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

2 PRODUCT

Product trade mark or trade name	LoFric Hydro-Kit
Reference no.	42106xx (discontinued during 2013), 42108xx, 42110xx 42308xx, 42310xx, 42312xx, 42314xx, 42316xx, 42318xx 42008xx, 42010xx, 42012xx, 42014xx, 42016xx, 42018xx 42510xx, 42512xx, 42514xx, 42516xx, 42518xx
Description	Single use urinary catheter with bag and water sachet
Country of origin	Sweden
Intended use of the product	The LoFric Hydro-Kit 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
Cassification rule?	Rule no. 5
Are handling instructions provided with the device?	Yes, on the carton (Customer box)

3 MATERIALS

Catheter (including connector) material	Polyolefin-based elastomer (POBE)
Coating material	Polyvinyl pyrrolidone (PVP), sodium chloride (NaCl)
Water sachet material	Laminate foil of polyethylene (PE), aluminium and polyethylene terephthalate (PET)
Collection bag material	Polyethylene butylacrylate (EBA)

4 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 (Di2-ethylhexyl) phthalate?	No

* See also Latex Statement

5 PACKAGING AND STORAGE

Mode of delivery	Individual packaging 20 catheters per carton (Customer box) 2 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 (CH 08: 2 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 / Customer box / transport packaging):

- Cardboard:	No / Yes / Yes
- Paper:	No
- Glass:	No
- Metal:	No
- Latex:	No*
- Cotton:	No
- Organic:	No
- Plastic (type of plastic):	Polyethylene butylacrylate (EBA)/No/No
- Other:	-

* See also Latex Statement

6 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 11137, 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
Is the manufacturing facility for this	BS EN ISO 9001 / BS EN ISO

component ISO / EN approved?	13485

7 STERILISATION

Method of sterilisation:	Irradiation: E-beam
Can the product be resterilised?	No, re-sterilisation not allowed
Why can it not be resterilised?	LoFric Hydro-Kit 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)

8 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

9 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

10 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

11 WASTE HANDLING

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

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

Recycling label:

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