





TENDER MASTER FILE NO: TMF 126	ISSUE NO: 3.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Welland Barrier Spray (Bag-on-valve)		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Welland Barrier Spray (Bag-on-valve)
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom
Manufacturing Facility:	Flexible Medical Packaging Ltd Hightown Whitecross Industrial Estate Lancaster LA1 4XQ United Kingdom
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Welland Barrier Spray (Bag-on-valve) is provided in an aerosol spray format. Each aerosol can contains a fluid comprising a blend of volatile silicones and a film-forming silicone resin. The 'Bag on valve' (BOV) system involves the fluid being contained within an inner bag and the propulsion of the aerosol is effected by a compressed gas (nitrogen) between the bag and the can. Depressing the actuator allows the fluid to form the aerosol spray. A major advantage of this system is that it delivers the aerosol spray at ambient temperature, avoiding the cold shock associated with hydrocarbon propelled aerosols.

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Welland Barrier Spray (Bag-on-valve)		PAGE 2 OF 3

	 <p><i>Figure 1: Welland Barrier Spray (Bag-on-valve)</i></p>
Indications for Use:	Welland Barrier Spray (Bag-on-valve) is intended to form a film to protect human skin from the effects of faecal material, urine and the damage that may be caused by the frequent application and removal of adhesive materials.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WBS050
Latex Statement:	Welland Barrier Spray (Bag-on-valve) does not contain natural rubber latex.
Listing of Main Components:	Hexamethydisiloxane Cyclomethicone (Decamethylcyclopentasiloxane) Dow Corning MQ-1600 Solid Resin
Listing of Primary Packaging Materials:	Welland Barrier Spray (Bag-on-valve) is provided in an aluminium can, with a polypropylene cap, nylon moving parts and nitrogen propellant.

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Welland Barrier Spray (Bag-on-valve)		PAGE 3 OF 3

GMDN code	58978
GMDN Description	Synthetic-polymer liquid barrier dressing, non-sterile
Shelf Life:	3 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	Cytotoxicity study showed no evidence of causing cell lysis or toxicity
Environmental Statement:	Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Keep away from sources of ignition. Keep out of reach of children. No smoking.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 126
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-WBS