

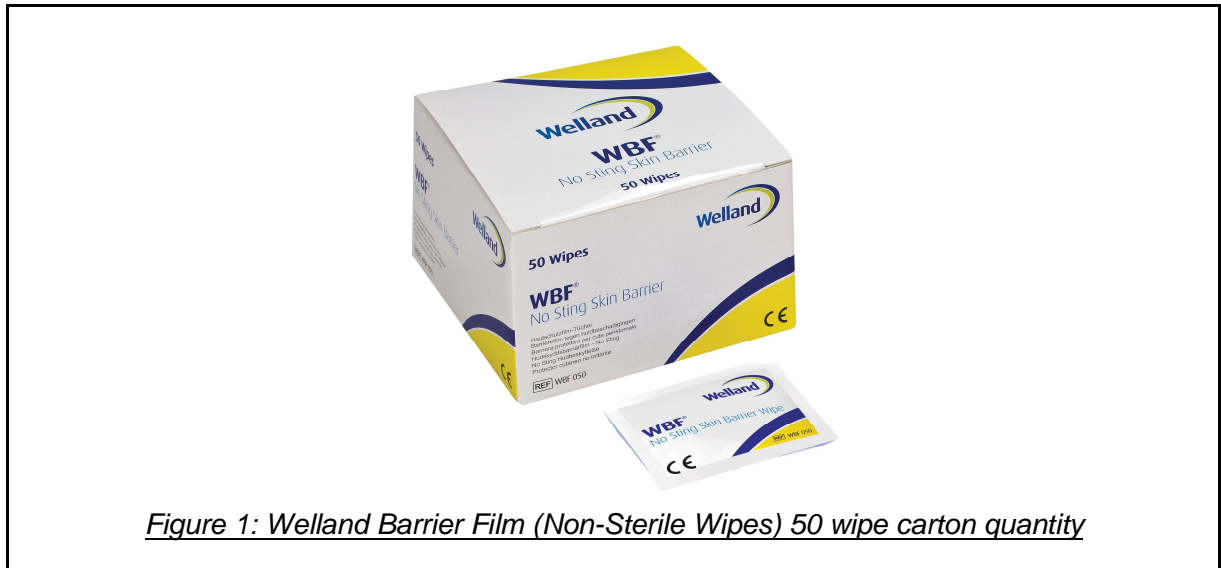



TENDER MASTER FILE NO: TMF 084	ISSUE NO: 4.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Welland Barrier Film® (Non-Sterile Wipes)		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Welland Barrier Film® (Non-Sterile Wipes)
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley West Sussex RH10 9AS United Kingdom
Manufacturing Facility:	Flexible Medical Packaging Ltd. Hightown, Whitecross Industrial Estate, Lancaster, LA1 4XQ
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Welland Barrier Film (Non-Sterile Wipes) is an impregnated non-woven material contained in a sealed sachet, presented in a carton quantity of 50 or 30 units. Each wipe is impregnated with a non-sting, silicone-based formulation which, when applied by hand, creates a film on the skin. The film dries in seconds by the evaporation of solvents, producing a breathable membrane which, in turn, provides a suitable surface for the application of adhered dressings and medical devices.

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Indications for Use:	Welland Barrier Film (Non-Sterile Wipes) is intended 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:	WBF050 (50 individually sealed wipes) WBF030 (30 individually sealed wipes)
Latex Statement:	Welland Barrier Film (Non-Sterile Wipes) is not made with natural rubber latex.
Listing of Main Components:	Hexamethyldisiloxane Cyclomethicone (Decamethylcyclopentasiloxane) Dow Corning MQ-1600 Solid Resin Non-woven tissue material

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Listing of Primary Packaging Materials:	Sachet material - Paper/Foil/Polyethylene 50 sachets per carton (<i>WBF050</i>) 30 sachets per carton (<i>WBF030</i>)
GMDN codes	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 concluded that the product showed no evidence of causing cell lysis or toxicity
Environmental Statement:	Highly flammable. However, small volume of solvents evaporates quickly after opening sachet and wipes can be disposed of in normal household waste. Wipes should not be flushed down the toilet.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 084
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-WF5 (<i>WBF050</i>) PPR-INS-WF3 (<i>WBF030</i>)