





TENDER MASTER FILE NO: TMF 123	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Welland Stoma Powder (25g)		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Welland Stoma Powder (25g)
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom
Manufacturing Facility:	Focus Product Developments Ltd Brian Royd Mills Saddleworth Road Greetland Halifax West Yorkshire HX4 8NF United Kingdom
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Welland Stoma Powder (25g) is a hydrocolloid powder, a blend of carboxymethylcellulose, pectin and starch, with Aloe Vera mixed in, supplied in a 25g bottle with a spout to aid application.

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Welland Stoma Powder (25g)		PAGE 2 OF 3

	
	<i>Figure 1: Welland Stoma Powder (25g)</i>
Indications for Use:	Welland Stoma Powder (25g) is intended to protect broken and weeping skin by absorbing moisture and creating a sticky gel which will allow an ostomy pouch to adhere to the skin.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WPP025
Latex Statement:	Welland Stoma Powder (25g) does not contain natural rubber latex.
Listing of Main Components:	Carboxymethylcellulose Pectin Starch Aloe Vera

TENDER MASTER FILE NO: TMF 123	ISSUE NO: 2.0	
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Welland Stoma Powder (25g)		PAGE 3 OF 3

Listing of Primary Packaging Materials:	Welland Stoma Powder (25g) is supplied in a plastic bottle with a spout to aid application. Twenty five bottles are placed in a grip seal bag, and four bags are placed in a shipper.
GMDN code	46207
GMDN Description	Peristomal/periwound dressing
Shelf Life:	3 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	May cause slight irritation
Environmental Statement:	Not considered an environmental hazard. Dispose of with normal household waste.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 123
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	WPP 025