





TENDER MASTER FILE NO: TMF 118	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Welland Stoma Paste		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Welland Stoma Paste
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom
Manufacturing Facility:	Alcare Co., Ltd 19F Arcacentral Bldg. 1-2-1 Kinshi Sumida-ku Tokyo 130-0013 Japan
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Welland Stoma Paste is a hypo-allergenic alcohol free paste designed to be spread onto uneven skin to provide an even surface for the application of an ostomy pouch. It is supplied in squeezable 20g and 100g tubes.

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	<i>Figure 1: Welland Stoma Paste</i>
Indications for Use:	Welland Stoma Paste is intended for use with ostomy pouches to help fill dips and gaps immediately around the stoma.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WSP020 (20g) WSP100 (100g)
Latex Statement:	Welland Stoma Paste does not contain natural rubber latex.
Listing of Main Components:	Pectin Sucrose Polybutene Amorphous silicon dioxide Psyllium husk powder Liquid polyisoprene Guar gum Karaya gum

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Listing of Primary Packaging Materials:	Polyethylene tube with a polypropylene cap.
GMDN code	46207
GMDN Description	Peristomal/periwound dressing
Shelf Life:	5 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	Weak irritation (Primary Irritation Index = 0.6)
Environmental Statement:	Not considered an environmental hazard. Dispose of with normal household waste.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 118
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	WSP 020 WSP 100