





TENDER MASTER FILE NO: TMF 125	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Welland Barrier Cream (100g)		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Welland Barrier Cream (100g)
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom
Manufacturing Facility:	Finesse Medical Ltd Unit 4 Royal Canal Business Park Athlone Road Longford Ireland
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Welland Barrier Cream (100g) is designed to form a long lasting watertight skin barrier which prevents and helps to heal irritated skin from the moisture and abrasion damage that can result from the removal and reapplication of ostomy pouches.

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Welland Barrier Cream (100g)		PAGE 2 OF 3

	
	<p><i>Figure 1: Welland Barrier Cream (100g)</i></p>
Indications for Use:	Welland Barrier Cream (100g) is intended to provide protection and moisturise skin when used with ostomy pouches.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WBC100
Latex Statement:	Welland Barrier Cream (100g) does not contain natural rubber latex.
Listing of Main Components:	Purified water Methylparaben Propylparbens Zinc oxide Disodium EDTA Sodium chloride Dimethicone Petrolatum Cetyl dimethicone Bees wax Cetyl Peg/PPG-10/1-dimethicone Propylene glycol Isopropyl palmitate Hydrogenated castor oil

TENDER MASTER FILE NO: TMF 125	ISSUE NO: 2.0	
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Welland Barrier Cream (100g)		PAGE 3 OF 3

Listing of Primary Packaging Materials:	Welland Barrier Cream (100g) is packaged in a high density polyethylene (HDPE) tube, with a polypropylene cap. Each tube is supplied in an individual carton.
GMDN code	46207
GMDN Description	Peristomal/periwound dressing
Shelf Life:	3 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	Mild reactivity (Primary Irritation Index = 0.9)
Environmental Statement:	Not considered an environmental hazard. Dispose of with normal household waste.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 125
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-WBC