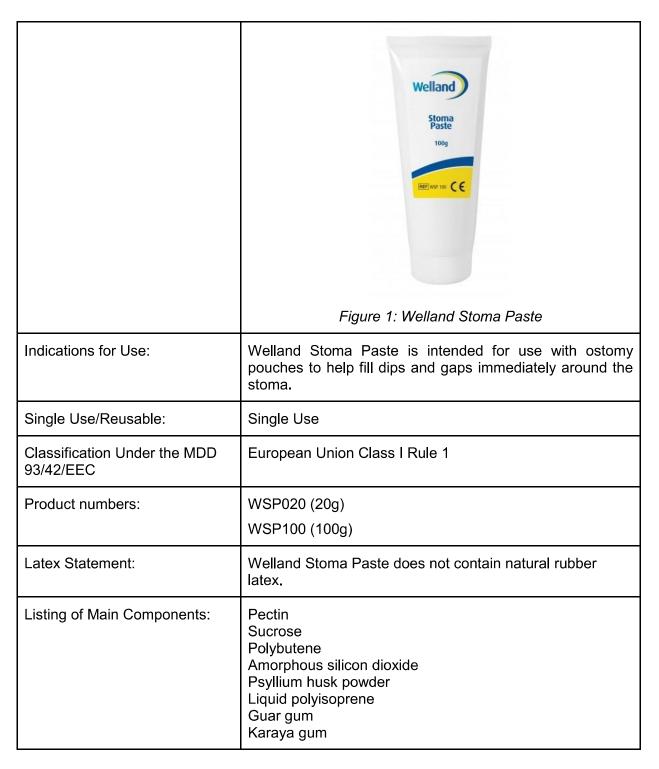
TENDER MASTER FILE NO: TMF 118	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
Welland Stoma Paste		PAGE 1 OF 3

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.	

TENDER MASTER FILE NO: TMF 118	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
Welland Stoma Paste		PAGE 2 OF 3



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

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	