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PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		
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Product Tender Master File	
Product Name:	UltraFrame®
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom
Manufacturing Facility:	Kyowa Limited 69-2 Takenouchicho, Takatsuki-city Osaka Japan
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	<p>UltraFrame (Ultra-thin flange extender) is a single-use, conformable ostomy accessory designed to provide extra security to the peripheral edges of an ostomy pouch flange. Consisting of polyurethane film and medical grade acrylic adhesive, the high conformability and instant high tack provide a secure attachment, rendering it beneficial for use around anatomical irregularities and skin folds. 20 units of UltraFrame are packaged into a transparent PET thermoformed clam pack.</p> <p>The product is waterproof, meaning it can be worn during bathing and swimming, and breathable, which may improve user comfort and help maintain healthy skin condition. The thinness and transparency of the product contribute to its discreteness.</p>


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Figure 1: UltraFrame




Figure 2: UltraFrame packaged in clam pack

Indications for Use:	UltraFrame is primarily intended for ostomates who experience conformity issues with their ostomy flange, such as seepage and/or a tendency to peel. Such issues can be brought about by physical activity, skin condition and/or anatomy shape around the stoma site.
Single Use/Reusable:	Single Use

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Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	(X)UFWAFH33 The prefix 'X' is used for export markets
Latex Statement:	UltraFrame is not made with natural rubber latex.
Listing of Main Components:	Medical grade acrylic adhesive Polyurethane film Paper release liner Polyethylene terephthalate release film Oriented polypropylene release film
Listing of Primary Packaging Materials:	Polyethylene terephthalate (PET) clam pack
GMDN code	46207
GMDN Description	Peristomal/Periwound dressing
Shelf Life:	3 years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	A crescent shaped flange extender comprising an adhesive coated polyurethane (PU) film with two polypropylene (PP) tabs to allow for ease of product removal. This is laminated with a silicone coated release paper on one side and a film with a polyethylene terephthalate (PET) central release tab on the other. The release paper is slit across the width at both ends for ease of removal and placement of the product around a flange.
Biocompatibility Data:	UltraFrame showed no cytotoxicity in cultured mammalian cells, was categorized as a 'slight' irritant with a Primary Irritation Index of 0.2, and was defined as 'negative' under

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	the skin sensitization test.
Environmental Statement:	UltraFrame can be disposed of in normal household waste or clinical waste

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 182
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-UF1