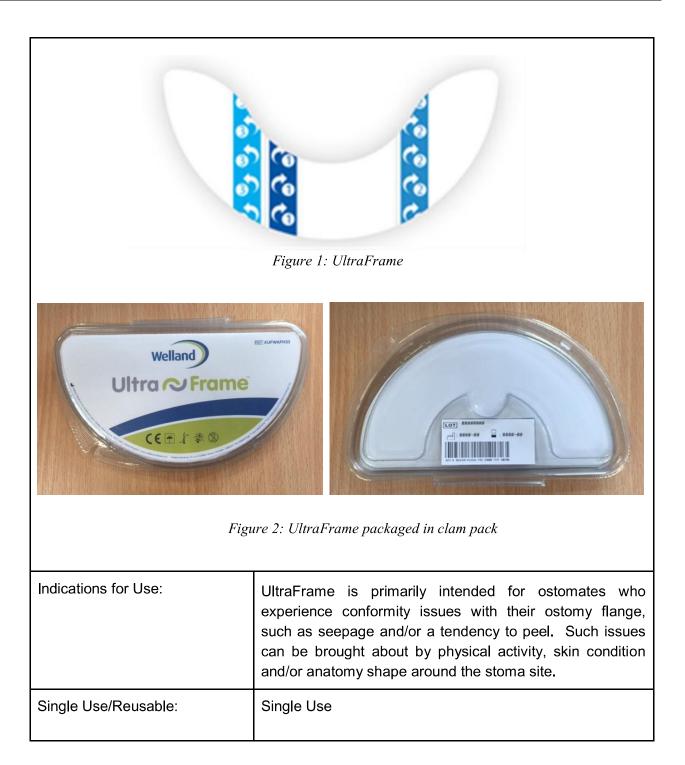
TENDER MASTER FILE NO: TMF 182	ISSUE 1.0	
PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
UltraFrame <sup>®</sup>		PAGE 1 OF 4

Product Tender Master File		
Product Name:	UltraFrame <sup>®</sup>	
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:	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.  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.	

TENDER MASTER FILE NO: TMF 182	ISSUE 1.0	
PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
UltraFrame <sup>®</sup>		PAGE 2 OF 4



TENDER MASTER FILE NO: TMF 182	ISSUE 1.0	
PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
UltraFrame <sup>®</sup>		PAGE 3 OF 4

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

TENDER MASTER FILE NO: TMF 182	ISSUE 1.0	
PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
UltraFrame <sup>®</sup>		PAGE 4 OF 4

	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	