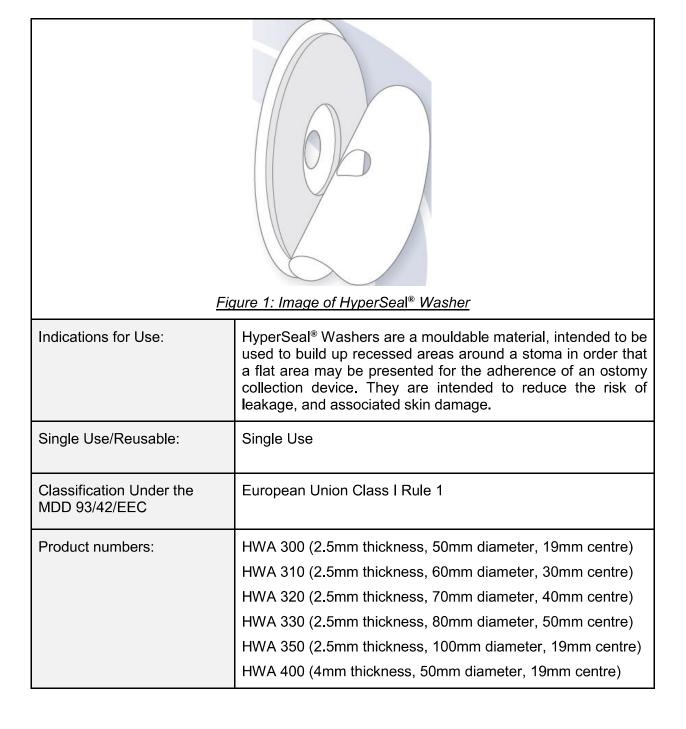
TENDER MASTER FILE NO: TMF 038	ISSUE NO: 2.0	
PREPARED BY: Beata Lesiak		Welland Medical
PROCESS OWNER: REGULATORY AFFAIRS		
HyperSeal® Washers		PAGE 1 OF 3

Product Tender Master File		
Product Name:	HyperSeal® Washers	
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom	
Manufacturing Facility:	Welland Medical Limited Hydehurst Lane Crawley RH10 9AS United Kingdom	
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom	
Notified Body Number:	0088	
Product Description:	HyperSeal® Washers are 50, 60, 70, 80 or 100mm diameter washer units with a 19, 30, 40 and 50mm centre aperture, manufactured as a hydrocolloid formulation extruded to a thickness of 2.5 or 4mm between two layers of release paper. The release paper is slightly wider than the washer to prevent the hydrocolloid from sticking to the packaging. The washers are individually packed in protective sealed blisters.	

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HyperSeal [®] Washers		PAGE 3 OF 3

Latex Statement:	HyperSeal® Washers are not made with natural rubber latex.
Listing of Main Components:	Release paper Hydrocolloid
Listing of Primary Packaging Materials:	PVC blister trays Paper blister lids
GMDN codes	31071
GMDN Description	Ostomy adhesive plate
Shelf Life:	3 years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Porcine gelatine is used in the hydrocolloid formulation of HyperSeal® Washers
Biocompatibility Data:	Cytotoxicity studies have confirmed the hydrocolloid formulation is safe and hypo-allergenic
Environmental Statement:	HyperSeal® Washers can be disposed of in normal household waste or clinical waste

Listing of Referenced Documentation		
Description	Comment(s)	
Declaration of Conformity	DOC 038	
Quality Management System:	Certificate No: LRQ 0946192	
Instructions for Use:	PPR-INS-W01 / PCT-BOX-F30 / PCT-BOX-F31	