



TENDER MASTER FILE NO: TMF 166	ISSUE NO: 2.0	
PREPARED BY: Beata Lesiak PROCESS OWNER: REGULATORY AFFAIRS		
HyperSeal® Washers with Manuka Honey		PAGE 1 OF 3

Product Tender Master File	
Product Name:	HyperSeal® Washers with Manuka Honey
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 with Manuka Honey 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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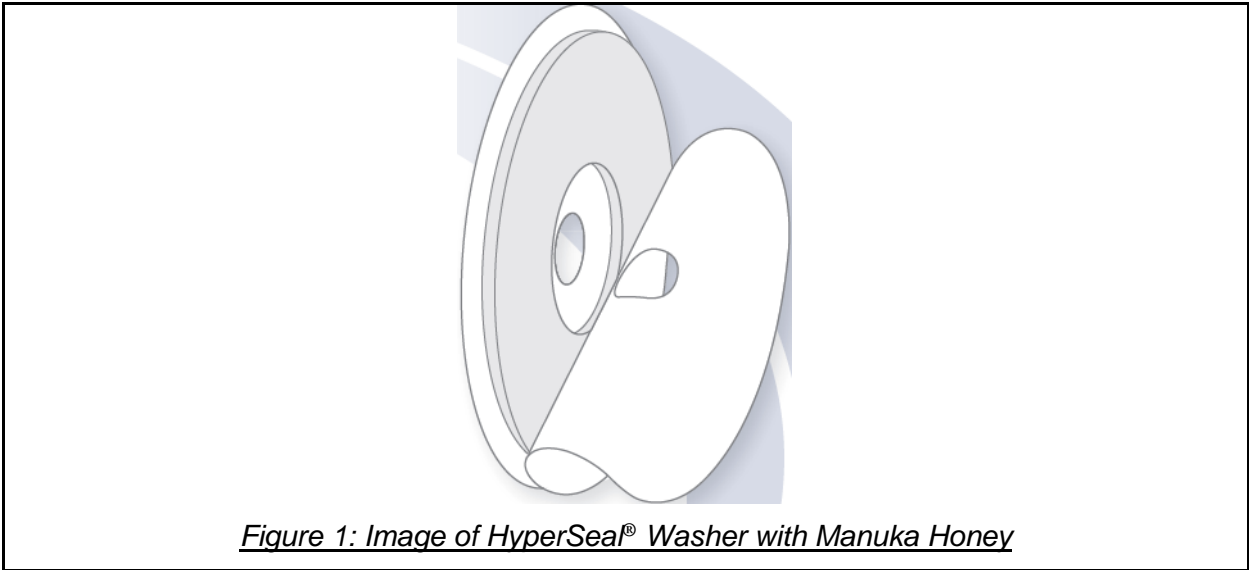



Figure 1: Image of HyperSeal® Washer with Manuka Honey

Indications for Use:	HyperSeal® Washers with Manuka Honey are a mouldable material, intended to be used to build up recessed areas around a stoma in order that a flat area may be presented for the adherence of an ostomy collection device. They are intended to reduce the risk of leakage, and associated skin damage. The introduction of medical grade Manuka Honey may help to promote healthy skin around the stoma.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	(X)MHWA300 (2.5mm thickness, 50mm diameter, 19mm centre) (X)MHWA310 (2.5mm thickness, 60mm diameter, 30mm centre) (X)MHWA320 (2.5mm thickness, 70mm diameter, 40mm centre) (X)MHWA330 (2.5mm thickness, 80mm diameter, 50mm centre) (X)MHWA350 (2.5mm thickness, 100mm diameter, 19mm centre) (X)MHWA400 (4mm thickness, 50mm diameter, 19mm centre) <i>The prefix 'X' is used for export markets</i>

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Latex Statement:	HyperSeal® Washers with Manuka Honey 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 and medical grade Manuka honey are used in the hydrocolloid formulation of HyperSeal® Washers with Manuka Honey
Biocompatibility Data:	Cytotoxicity studies have confirmed the hydrocolloid formulation is safe and hypo-allergenic
Environmental Statement:	HyperSeal® Washers with Manuka Honey can be disposed of in normal household waste or clinical waste

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 166
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-W01 / PCT-BOX-F30 / PCT-BOX-F31