



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


<b>Product Tender Master File</b>	
Product Name:	<b>HyperSeal® Washers</b>
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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*Figure 1: Image of HyperSeal® Washer*

Indications for Use:	HyperSeal® Washers 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.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	HWA 300 (2.5mm thickness, 50mm diameter, 19mm centre) HWA 310 (2.5mm thickness, 60mm diameter, 30mm centre) HWA 320 (2.5mm thickness, 70mm diameter, 40mm centre) HWA 330 (2.5mm thickness, 80mm diameter, 50mm centre) HWA 350 (2.5mm thickness, 100mm diameter, 19mm centre) HWA 400 (4mm thickness, 50mm diameter, 19mm centre)

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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

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