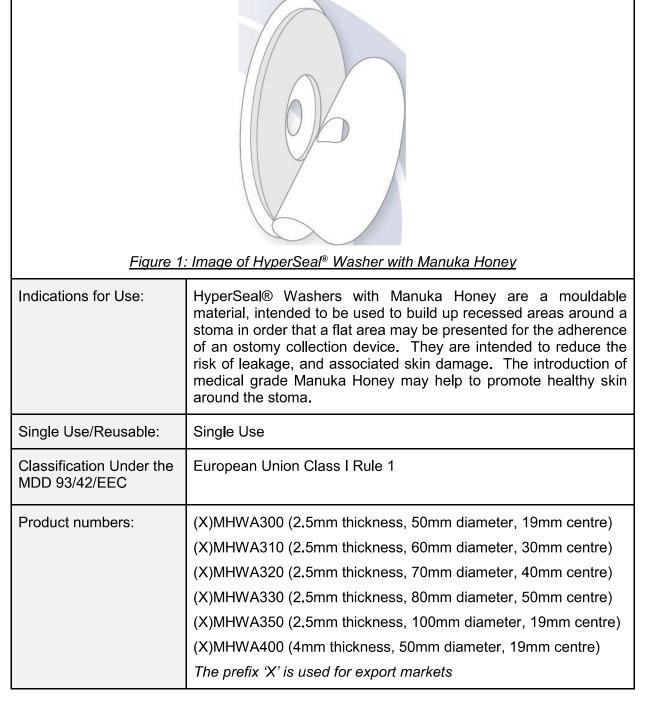
| TENDER MASTER FILE NO: TMF 166 | ISSUE NO: 2.0 | |
|--|---------------|--------------------|
| PREPARED BY: Beata Lesiak | | Welland Medical |
| PROCESS OWNER: REGULATORY AFFAIRS | | |
| HyperSeal [®] Washers with Manuka Honey | | PAGE 1 OF 3 |

| 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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| HyperSeal [®] Washers with Manuka Honey | | PAGE 2 OF 3 |



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|--|---------------|-------------|
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| HyperSeal [®] Washers with Manuka Honey | | PAGE 3 OF 3 |

| 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 | |