TENDER MASTER FILE NO: TMF 057	ISSUE NO: 2.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
HydroFrame®		PAGE 1 OF 3

Product Tender Master File

Product Name:	**HydroFrame®**
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 Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	HydroFrames® are flange extension medical device accessories intended for use on patients who have a Colostomy, Ileostomy or Urostomy pouch and who have a requirement for extra security around the flange.

Figure 1: Image of HydroFrame®

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Indications for Use:	HydroFrames® are designed to be fixed adhesively to the edge of the flange where there may be a tendency for the flange to peel away and cause leakage particularly during physical activity or if worn on irregular skin.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WAFH33 (UK market) XWAFH33 (Export market)
Latex Statement:	HydroFrames® are not made with natural rubber latex.
Listing of Main Components:	Release paper Hydrocolloid Polyurethane backing
Listing of Primary Packaging Materials:	PVC Clampack (PCT-PAC-A13)  *Figure 2: Image of Clampack*
GMDN codes	31071

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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 the HydroFrames®.
Biocompatibility Data:	Hydrocolloid is safe and hypo-allergenic.
Environmental Statement:	HydroFrames® can be disposed of in normal household waste or clinical waste.

Listing of Referenced Documentation	
Description	**Comment(s)**
Declaration of Conformity	DOC 057
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-HUK (UK market) PPR-INS-HXX (Export market)

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