




TENDER MASTER FILE NO: TMF 083	ISSUE NO: 5.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Medical Adhesive Remover Wipes		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Medical Adhesive Remover Wipes
Legal Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley West Sussex RH10 9AS United Kingdom
Manufacturing Facility:	Flexible Medical Packaging Ltd. Hightown, Whitecross Industrial Estate, Lancaster. LA1 4XQ
Notified Body:	LRQA UK 1 Trinity Park Bickenhill Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Medical Adhesive Remover Wipes are wipes impregnated with a silicone based adhesive remover. Each wipe is contained in a sealed sachet.

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Indications for Use:	Medical Adhesive Remover Wipes are intended to remove adhesive from the skin without causing a stinging effect or leaving a residue.
Single Use/Reusable:	Single Use
Classification Under the MDD 93/42/EEC	European Union Class I Rule 1
Product numbers:	WAD050 (50 individually sealed wipes) WAD060 (60 individually sealed wipes)
Latex Statement:	Medical Adhesive Remover Wipes are not made with natural rubber latex.
Listing of Main Components:	Hexamethyldisiloxane Octamethyltrisiloxane Cyclomethicone (Decamethylcyclopentasiloxane)

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Listing of Primary Packaging Materials:	Sachet – Paper / Polyethylene / Aluminium / Surlyn
GMDN codes	10033
GMDN Description	Medical adhesive remover, non-sterile
Shelf Life:	3 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	Medical Adhesive Remover Wipes passed a cytotoxicity test with 'mild reactivity'
Environmental Statement:	Highly flammable. However, small volume of solvents evaporates quickly after opening sachet and wipes can be disposed of in normal household waste. Wipes should not be flushed down the toilet.

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 083
Quality Management System	Certificate No: LRQ 0946192
Instructions for Use	PPR-INS-WAD