





TENDER MASTER FILE NO: TMF 127	ISSUE NO: 4.0	
PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		
Medical Adhesive Remover Spray		PAGE 1 OF 3

Product Tender Master File	
Product Name:	Medical Adhesive Remover Spray
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 Lane Birmingham B37 7ES United Kingdom
Notified Body Number:	0088
Product Description:	Medical Adhesive Remover Spray is presented in a 50ml can, and the active ingredient is sprayed onto the edge of the adhesive flange of an ostomy bag to reduce the bond strength which makes it easier to remove the flange from the skin. The Bag-on-valve system consists of an aerosol valve with a welded bag. The adhesive remover is placed inside the bag while the propellant is filled in the space between the bag and the can.

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	<p><i>Figure 1: Medical Adhesive Remover Spray</i></p>
Indications for Use:	Medical Adhesive Remover Spray is 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:	WAB050
Latex Statement:	Medical Adhesive Remover Spray is not made with natural rubber latex.

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Listing of Main Components:	Hexamethyldisiloxane Octamethyltrisiloxane Cyclomethicone (Decamethylcyclopentasiloxane)
Listing of Primary Packaging Materials:	Aluminium can with polypropylene cap and nylon moving parts. Nitrogen propellant
GMDN code	10033
GMDN Description	Adhesive tape remover
Shelf Life:	3 Years
Coatings/ Materials of animal Origin/ Medicinal / Other Substances:	Not applicable
Biocompatibility Data:	Mild reactivity
Environmental Statement:	Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Keep away from sources of ignition. Keep out of reach of children. No smoking

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity	DOC 127
Quality Management System:	Certificate No: LRQ 0946192
Instructions for Use:	PPR-INS-WAB