

Product Specifications PS WAB	ISSUE NO: 6.0	
Medical Adhesive Remover Care Accessories, Ostomy Devices – Accessories, No Sting, Spray		

Product Information	
Product Name:	Medical Adhesive Remover
Manufacturer:	Welland Medical Limited Hydehurst Lane Crawley West Sussex RH10 9AS United Kingdom
Product Description:	Medical Adhesive Remover, no sting spray belongs to Welland's Care accessories range. The accessory 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. Figure 1: Medical Adhesive Remover, spray 50ml
Intended Use:	Removes ostomy appliance adhesive from the skin.
Indications for Use:	For use on intact skin only. Removes adhesive from the skin without causing a stinging effect or leaving a residue.

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Warnings:	Use only as directed. Avoid use on delicate or sensitive areas of skin (eyes, mouth, ears, nose, vagina). If in doubt patch test a small area prior to use. Discontinue use if irritation occurs. This product may not be suitable for use on babies under 30 days old. Avoid direct inhalation or use in enclosed spaces. The spray is flammable indicated by a symbol on the can and carton. WARNING! 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. In the event of a serious incident, seek medical advice before contacting manufacturer, Welland Medical Ltd., and your local Competent Authority via your distributor or importer.
Single Use/Reusable:	Single patient, multiple use The aerosol contains 50ml of the fluid solution; each aerosol spray is anticipated to be used for multiple applications.
Classification Under the EU/2017/745 MDR:	Class I
Product Codes:	WAB050
Listing of Main Components:	Hexamethyldisiloxane Octamethyltrisiloxane Cyclomethicone (Decamethylcyclopentasiloxane)
Packaging:	Cardboard outer carton, containing an aluminium can with polypropylene cap and nylon moving parts. Nitrogen propellant
GMDN Code:	60494
GMDN Description:	Patient medical adhesive remover
CND Code:	A1080
CND Description:	Ostomy Devices - Accessories
EMDN Code:	A108005
EMDN Description:	Devices for the Removal of Adhesives from the Peristomal Skin

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Shelf Life:	3 Years
Materials of animal Origin:	Not applicable
Biocompatibility Data:	Biological safety has been demonstrated.
Environmental Statement:	Pressurised container. Highly flammable. Empty cans and carton can be disposed of in normal household waste

Listing of Referenced Documentation	
Description	Comment(s)
Declaration of Conformity:	DOC Medical Adhesive Remover
Quality Management System:	Certificate No: GB19/964922
Instructions for Use:	PPR-INS-WAB-ROW PPR-INS-WAB-DAC