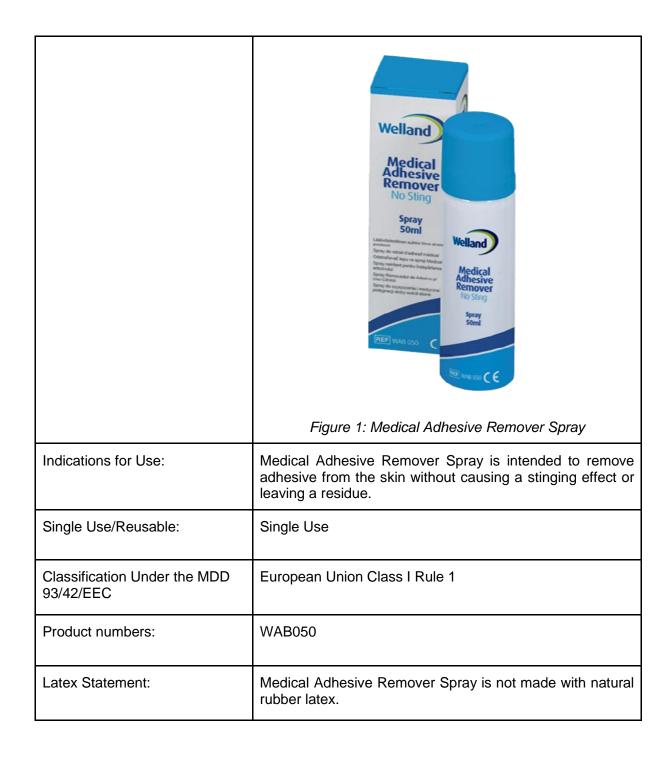
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PREPARED BY: Kim Dodman PROCESS OWNER: REGULATORY AFFAIRS		Welland Medical
Medical Adhesive Remover Spray		PAGE 1 OF 3

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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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	