




Declaration of Conformity

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	ADHESIVE REMOVER SPRAY
Legal Manufacturer: (Name on Label)	Silmed Limited Earl Mill, Dowry Street, Oldham, Manchester, OL8 2PF United Kingdom
Basic UDI-DI:	506040385SIL077
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Non-sting Medical Adhesive Remover Spray is intended to remove adhesive from the skin without causing a stinging effect or leaving a residue
MDR Classification:	Class I [Rule 1]
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of a Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745

Name Andrew Micklethwaite **Position** Director

Signed  **Date** 31-AUG-2021 **Place** UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1 General Requirements

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN Code
SIL-102	Medical Adhesive Remover (Hungarian)	10033

Version History

Version	Compiled by	Date	Description
1	A Micklethwaite	31/08/2021	New document