

EU DECLARATION OF CONFORMITY – REGULATION 2017/745

Number 020

Manufacturer: OxMed International GmbH
 Groendahlscher Weg 87
 46446 Emmerich am Rhein
 Germany

Eudamed SRN: DE-MF-000004970

Products: **ZenSetiv Adhesive Remover Spray 50ml**
 See Schedule of Products on page 2 for the code.

Basic UDI-DI 4260333ACC-RSB9

Intended Purpose: ZenSetiv Adhesive Remover Spray is specially formulated and intended for the safe and pain free removal of medical adhesives from the skin.
 ZenSetiv Adhesive Remover Spray can be used to aid removal of, for example, wound dressings, tapes and stoma flanges and is effective for removing areas of adhesive build up on the skin.

Risk Class Class I as per MDR 2017/745 Annex VIII Chapter III – Rule 1.

Statements: The product is not sterile, does not have a measuring function and is not a reusable surgical instrument.

OxMed International GmbH declares, under our sole responsibility, that the device listed on the attached Device Schedule conforms to the relevant provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council dated 5th April 2017 on medical devices, and all relevant amendments, and is in accordance with Annex IX, Chapter I excluding 3, Annex II and Annex III.

Relevant Standards:

| Standard | Description |
|---------------------|---|
| EN ISO 14971:2019 | Medical Devices – Application of Risk Management to Medical Devices |
| EN ISO 15223-1:2021 | Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General Requirements |
| ISO 20417:2021 | Medical devices - Information supplied by the manufacturer |

Place and Date of Issue: Emmerich am Rhein, Germany. 6th January 2022

Signed:



J.C.H. van Kerkhof, Managing Director, OxMed International GmbH


SCHEDULE OF PRODUCTS

| Product Code | Product Description |
|--------------|--------------------------------------|
| ZSA2011 | ZenSetiv Adhesive Remover Spray 50ml |
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