Declaration of Conformity

Per EU MDR 2017/745

Manufacturer Avery Dennison Medical Ltd.

Address IDA Business Park,
Ballinalee Road,
Longford, N39 DX73,
Ireland

Single Registration Number IE-MF-000001926

Authorized Representative Not Applicable

Medical Device Description Hydrogel Wound Dressing is an amorphous, sterile, translucent, colourless and clear primary dressing made from a modified starch polymer, glycerol, preservatives and water. The benefits and features of Hydrogel are:

- It provides a moist environment at the wound surface and assists in the debridement and removal of necrotic and other devitalised material from low exuding wounds.
- Hydrogel can also be used to soften and hydrate necrotic tissue, helping to rehydrate dry granulating wounds.

Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number
Hydrogel	IIb	Rule 4	Annex IX QMS and Technical Documentation	738647

Basic UDI 0081713801TF030K3

Intended Purpose Long term, non-invasive wound dressings intended principally for the management of most types of ulcers, pressure sores and other low exuding sloughy or necrotic wounds.

Indication Hydrogel is indicated for the management of dry non exuding wounds and also moderately exuding, partial thickness wounds, such as

- pressure ulcers
- venous leg ulcers
- diabetic foot ulcers
- first and second degree burns
- incontinence dermatitis

Gel is not intended for use in babies under 12 weeks old.

Notified Body BSI, The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands

Notified Body Number 2797

Declaration of Conformity

Per EU MDR 2017/745

Avery Dennison Medical Ltd.; declares that the above documented products meet the provision of the council regulation 2017/745. This declaration authorises Avery Dennison Medical to affix the CE-mark to the products listed herein. This declaration is supported by compliance with the general safety and performance requirements by meeting the harmonised standards outlined in Attachment 2.

We, hereby declare that this declaration of conformity is issued under the sole responsibility of Avery Dennison Medical Ltd.

Name and Title	Signature and Date
Elaine Minagh Regulatory Affairs Manager	Elaine Minagh 30 MAY 2023
Place of issue	**Date of issue**
Longford, Ireland	Captured on Master Control

Declaration of Conformity

Per EU MDR 2017/745

Attachment 1: List of Product Codes

Description	Size	Units/ Box	Reference Number	CE Certification Date
Hydrogel	8g	5	ML250P080S05	05 May 2023
Hydrogel	8g	10	ML250P080S10	05 May 2023
Hydrogel (snap-off lid)	15g	10	ML2502P0150S10	05 May 2023
Hydrogel (screw lid)	15g	10	ML250P0150S10	05 May 2023
Hydrosorb Gel	8g	5	900 831	05 May 2023
Hydrosorb Gel	15g	10	900 832	05 May 2023

Declaration of Conformity

Per EU MDR 2017/745

Attachment 2: List of Harmonized Standards and Common Specifications

Standard/Regulation	Title
EN ISO 13485	Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 11737-1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN 556-1	Sterilisation of Medical Devices – Requirements for Medical Devices to be designated sterile - Part 1: Requirements for terminally -Sterile Medical Devices.
ISO 11135	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 14644-1	Cleanrooms and Associated Controlled Environments – Part1: Classification of Air Cleanliness.
EN ISO 14644-2	Cleanrooms and Associated Controlled Environments - Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1
EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 13726-1	Test Methods for Primary Wound Care Dressings – Part 1: Aspects of Absorbency
EN 13726-2	Test Methods for Primary Wound Care Dressings – Part 2: Moisture Vapour Transmission Rate of Permeable Film Dressings
EN ISO 1522	Medical device - symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN ISO 20417	Information supplied by the manufacturer of medical devices
IEC 62366-1	Medical devices. Application of usability engineering to medical devices
EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements.

Refer to current revisions of standards – GBL-LST-000006

Declaration of Conformity

Per EU MDR 2017/745

Revision History

Revision	Date	Revision History	Originator
A	19 May 2023	Initial document as per MDR 2017/745.	Patricia Slattery