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

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

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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	Eline Unagle 30 MA	1 2023	
Place of issue Date of issue			
Longford, Ireland	Captured on Master Control		

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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

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Attachment 2: List of Harmonized Standards and Common Specifications

EN ISO 13485 EN ISO 14971 Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes EN ISO 10993-1 EN ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity EN ISO 10993-5 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 Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterilization process Sterilization of nedical devices - Microbiological methods – Part 2: Tests of sterilization process Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterilization process Sterilization of Medical Devices – Requirements for Medical Devices to be designated sterile – Part 1: Requirements for terminally -Sterile Medical Devices. Sterilization of Medical Devices – Requirements for terminally -Sterile Medical Devices. 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 EN ISO 14644-1 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 Test Methods for Primary Wound Care Dressings – Part 2: Validation requirements for forming, sealing and assembly processes Test Methods for Primary Wound Care Dressings – Part 2: Moisture Vapour Transmission Rate of Permeable Film Dressings Medical devi	Standard/Regulation	Title	
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Refer to current revisions of standards – GBL-LST-000006

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Revision History

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

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