


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	<p>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:</p> <ul style="list-style-type: none"> • 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	MDR 738647
Basic UDI	081713801TF030XV			
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	<p>Hydrogel is suitable for the management of:</p> <ul style="list-style-type: none"> • ulcers, • pressure sores • other low exuding sloughy or necrotic wounds <p>Hydrogel by providing a moist environment at the wound surface, assists in the debridement and removal of necrotic and other devitalised material from low exuding wounds. The Hydrogel can be used to soften and hydrate necrotic tissue, helping to rehydrate dry granulating wounds. Hydrogel is suitable for the treatment of:</p> <ul style="list-style-type: none"> • first and second degree burns 			

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	<ul style="list-style-type: none">Incontinence dermatitis.
Notified Body	BSI, The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands
Notified Body Number	2797

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	 18 Mar 2026
Place of issue	Date of issue
Longford, Ireland	18/03/26

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Attachment 1: List of Product Codes

Description	Size	Units/ Box	Reference Number	CE Certificate Date	Basic UDI-DI
Hydrosorb Gel	8g	5	900 831	May 2023	00817138014355
Hydrosorb Gel	15g	10	900 832	May 2023	00817138014232

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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	Test methods for wound dressings. Aspects of absorption, moisture vapour transmission, waterproofness and extensibility
EN ISO 15223	Medical device - symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Information supplied by the manufacturer of medical devices
IEC 62366-1	Medical devices. Application of usability engineering to medical devices

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

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Revision History

Revision	Date	Revision History	Originator
A	18 Mar 2026	Initial document as per MDR 2017/745, created for registrations only	Patricia Slattery

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