

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	Barrier Film is a polymeric solution which forms a uniform film when applied to the skin. The product is dispersed in a non-stinging solvent, which dries rapidly. The film is colourless, transparent, and possesses good oxygen and moisture vapour permeability. Barrier Film helps to protect intact or damaged skin from irritation caused by urine and/or fecal incontinence, digestive juices and wound drainage. Barrier Film Spray is a multiple use device that is intended for single patient use													
<table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 25%;">Product Name</th> <th style="width: 25%;">Product Classification</th> <th style="width: 25%;">Classification Rule</th> <th style="width: 25%;">Conformity Pathway</th> <th style="width: 20%;">CE Certificate Number</th> </tr> </thead> <tbody> <tr> <td>Avery Dennison Barrier Film Swab, Wipe and Spray</td> <td>Ila</td> <td>4</td> <td>Annex IX - Quality Management System and Assessment of Technical Documentation</td> <td>MDR 738647</td> </tr> </tbody> </table>					Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number	Avery Dennison Barrier Film Swab, Wipe and Spray	Ila	4	Annex IX - Quality Management System and Assessment of Technical Documentation	MDR 738647
Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number										
Avery Dennison Barrier Film Swab, Wipe and Spray	Ila	4	Annex IX - Quality Management System and Assessment of Technical Documentation	MDR 738647										
Basic UDI (Barrier Film Swab & Wipe)	081713801TF006aWJ													
Basic UDI (Barrier Film Spray)	081713801TF006bWL													
Intended Purpose	Barrier Film is a liquid intended for use as a film-forming product that upon application to intact or damaged skin forms a long lasting waterproof barrier, which acts as a protective interface between the skin and bodily wastes and fluids. It is intended as a primary barrier against irritation from body fluids and can be used on adults and children.													
Indication	The products are indicated for protecting intact or damaged skin from body fluids for the following: <ul style="list-style-type: none"> Incontinence skin care Peri-stomal skin protection Peri-wound skin protection 													

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Notified Body	BSI Group 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 documented products meet the provision of the council regulation 2017/745. This declaration authorizes Avery Dennison 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 harmonized 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 Quality & Regulatory Affairs Manager	
Place of issue	Date of issue
Longford, Ireland	28/08/25

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Attachment 1: List of Product Codes

Table 1 Devices covered within the Technical Documentation TF006				
Description	Size	Unit /Box	Article Number	CE Certification Date
Hartmann MedProtect Film Swab	1ml	24	995103	08 Aug 2025
Hartmann MedProtect Film Spray	28 ml	12	995102	08 Aug 2025

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Attachment 2: LFD-GSPR-000005 and LFD-GSPR-000006: List of Harmonized Standards and Common Specification.

Standard Reference	Description
EN ISO 13485	Medical Devices - Quality Management Systems – Requirements for Regulatory Purposes
EN 556-1	Sterilisation of Medical Devices – Requirements for Medical Devices to be designated sterile - Part 1: Requirements for terminally -Sterile Medical Devices.
EN ISO 15223-1	Medical device - symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN 20417	Information supplied by the manufacturer of medical devices
EN 13726	Test methods for wound dressings. Aspects of absorption, moisture vapour transmission, waterproofness and extensibility
IEC 62366	Medical Devices - Application of Usability Engineering to Medical Devices
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects development, validation and routine control
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 ISO 14971	Medical devices - Application of risk management to medical devices
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

Refer to GBL-LST-000006 for current Standard Revision

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Revision History

Revision	Date	Revision History	Originator
A	18 May 2020	Initial Revision	E. Minagh
B	04 Feb 2022	Update of versions of standards ISO 15223 to 2021, add EN 20417:2021	P Slattery
C	18 Feb 2022	Added to table 1 barrier film Swab	P Slattery
D	13 July 2022	Update to remove Edition date from Standards	P Slattery
E	06 April 2023	Replaced Attachment 2 with LFD-GSPR-000005 & LFD-GSPR-000006	A.Boateng
F	28 Nov 2023	Addition of a separate Basic UDI for the Barrier Film Spray. CE Certification Date added to Attachment 1. Indication updated to remove: “in the areas of”.	A.Boateng
G	06 Mar 24	Correct Basic UDI from 0081713801TF006K6 to 081713801TF006K6aWJ 0081713801TF007K8 to 081713801TF006bWL	P Slattery
H	13 June 2024	Updates to Attachment 1 to include product Brand Names. Update to revised standard in Attachment 2.	A.Boateng
I	20 Jan 2025	Change of brand name section.	P Slattery
J	28 Aug 2025	Addition of MedProtect codes 995103, 995102	P Slattery

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