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 Cream is a white concentrated cream that provides protection to skin from body fluids. It protects dry, chafed, red, or irritated skin by moisturising the skin and providing a long lasting barrierUse of this cream allows adhesive products to stick to the skin. The cream is presented in a tube or sachet and is supplied non-sterile..

Product Name	**Product Classification**	**Classification Rules**	**Conformity Pathway**	**CE Certificate Number**
Barrier Cream	IIa	Rule 21, Rule 4	Annex IX Quality Management System and Assessment of Technical Documentation	MDR 738647

Basic UDI	081713801TF010XP
Intended Purpose	Barrier Cream protects at-risk skin areas from damage and irritation associated with incontinence. Barrier Cream maintains and preserves skin from damage associated with chronic incontinence. It moisturizes and protects severely dry skin. The cream will not reduce adhesion of medical tapes or adhesive dressings.
Indication	Barrier Cream is used for prevention of: • Incontinence-associated dermatitis • Prevention of skin breakdown linked to incontinence • Prevention of skin breakdown linked to bodily fluids • Moisturizing of severely dry skin.
Notified Body	BSI Group 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 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

Description	**Size**	**Units/ Box**	**Article Number / Ref**	CE Certification Date
Hartmann MedProtect Cream	28g Tube	12	995101	08 Aug 2025

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Attachment 2: LFD-GSPR-000008: List of Harmonized Standards and Common Specifications

Standard Reference	Description
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 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 13726	Test methods for wound dressings. Aspects of absorption, moisture vapour transmission, waterproofness and extensibility
EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements.
EN 20417	Information supplied by the manufacturer of medical devices
IEC 62366-1	Medical devices. Application of usability engineering to medical devices

Refer to GBL-LST-000006 for current Standard Revision

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Revision History

Revision	Date	Revision History	Originator
A	14 May 2020	Initial Revision The document is created to maintain compliance to the Regulation (EU) 2017/745.	E.Minagh
B	29 Mar 2021	Up-classification of Barrier Cream range from Class I to Class IIa, as defined by Rule 4 Annex VIII MDR 2017/745. Addition of brandname product range to scope. Addition of CE cert number, Basic UDI and SRN.	D.Casey
C	14 Jan 2022	Update to standards as per GBL-LST-000006.	D.Casey
D	21 Feb 2022	Replace rule 4 with rule 21 following BSI finding of technical review of TF010.	P Slattery
E	08 Apr 2022	Added rule 4 to classification rules, following BSI review of TF010 attachment 2 remove rev of standards and refer to GBL-LST-000006	P Slattery
F	05 April 2023	Attachment 1: List of Product Codes: Removed column with UDI assigned code to align with document layout Attachment 2 replaced with LFD-GSPR-000008	A.Boateng
G	03 July 2023	Updated Product description in Attachment 1: List of Product Codes and an additional column for CE Certification Date.	A. Boateng
H	17 June 2024	Update to correct Basic UDI from 0081713801TF010JV to 081713801TF010XP. Update to revised standards in Attachment 2. Medical device description and Indications updated to align with Barrier Cream Technical documentation.	A.Boateng
I	28 Aug 2025	Addition of Code 995101 barrier cream	P Slattery