By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 738647 R001

Manufacturer: Avery Dennison Medical Limited

Address:
IDA Business Park
Longford
N39 DX73
Ireland

Single Registration Number: IE-MF-000001926

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-01-06**

Current Issue Date: **2024-02-07**

Starting Validity Date: **2024-02-07**

Expiry Date: **2029-01-05**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Superabsorbent Wound Dressing	Intended principally for the management of moderately to heavily exuding, partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent.
Silicone Wound Contact Layer	Intended principally for the management of exuding partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent.
Hydrogel dressings	Intended principally for the management of most types of ulcers, pressure sores and other low exuding sloughy or necrotic wounds

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-01-06	3317570	Issued.
2022-07-29	3729686	Supplemented – Addition of device group: Barrier Creams.
2022-10-17	3772465	Supplemented – Addition of device group: Silicone Wound Contact Layer
2023-05-05	3896242	Supplemented – Addition of Hydrogel dressings Amended – Merging of "Barrier Film Devices (sterile and non-sterile)" and "Barrier Creams" into "Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)"
2023-12-15	30056854	Re-issued – Certificate renewal
Current	30104436	Amended – Addition of critical subcontractor for gamma sterilisation of Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)

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