



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
Ballinalee Road
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 Global Regulatory & Quality

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

Current Issue Date: **2025-02-05**

Starting Validity Date: **2025-02-05**

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

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

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

MDR 738647 R001

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
Adhesive Dressing with absorbent foam pad	Intended principally for the management of low to moderately exuding, partial to full thickness wounds which have breached the dermis on injured skin and can only heal by secondary intent

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

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

Current Issue Date: **2025-02-05**

Starting Validity Date: **2025-02-05**

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

...making excellence a habit.™



By Royal Charter

EU Quality Management System Certificate

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

MDR 738647 R001

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
2024-02-07	30104436	Amended – Addition of critical subcontractor for gamma sterilisation of Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)
2024-07-09	30203383	Supplemented – Addition of Adhesive Dressing with absorbent foam pad
Current	30315343	Amended – Addition of crucial supplier for barrier film solution Amended – Re-addition of missing line in the legal manufacturer address due to administrative error

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

Current Issue Date: **2025-02-05**

Starting Validity Date: **2025-02-05**

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

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.