



# 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 Starting Validity Date: 2024-02-07

Current Issue Date: **2024-02-07** Expiry Date: **2029-01-05** 

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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.





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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,	Class IIa	116
gels, fluids and creams)		

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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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