

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

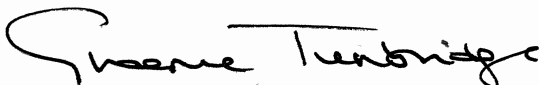
No. UKCA 785712
Issued To: Avery Dennison Medical Limited
IDA Business Park
Ballinalee Road
Longford
N39 DX73
Ireland

In respect of:

The design, manufacture and final inspection of sterile Hydrogel dressings, sterile barrier films and non-sterile barrier creams.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-09-07**

Date: **2023-12-15**

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

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Supplementary Information to UKCA 785712

Issued To:

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Device code	Device Name	Intended purpose per IFU
Class IIa		
MD 0303	Protective devices, lubricants and soothing devices (spays, gels, fluids and creams)	---
Class IIb		
MD 0301	Hydrogel dressings	Intended principally for the management of most types of ulcers, pressure sores and other low exuding sloughy or necrotic wounds

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Certificate History

Certificate No: **UKCA 785712**
Date: **2023-12-15**
Issued To: **Avery Dennison Medical Limited**
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Date	Reference Number	Action
2023-09-07	3853886	First Issue; Traceable to MDR 738647
Current	30056856	Certificate renewal

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