EU Quality Management System Certificate

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

MDR 732832 R002

Manufacturer: Smith & Nephew Medical Ltd

Address:
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Single Registration Number: GB-MF-000017580

EU Authorised Representative: Smith & Nephew Operations B.V.

Address:
Bloemlaan 2
2132 NP Hoofddorp
Netherlands

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: **2021-09-07**

Current Issue Date: **2026-09-02**

Starting Validity Date: **2026-09-07**

Expiry Date: **2031-09-06**

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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 Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
BIOBRANE porcine gelatin wound dressings and gloves	See MDR 733300
Durafiber Ag	See MDR 737177
ALLEVYN Ag Adhesive	See MDR 737178
ALLEVYN Ag Non-adhesive	See MDR 737179
ALLEVYN Ag Gentle Border	See MDR 737180
ACTICOAT Flex 3	See MDR 737184
ACTICOAT Flex 7	See MDR 737183
ACTICOAT/ARGENCOAT	See MDR 737185
ACTICOAT 7	See MDR 737197
IODOSORB Dressing	See MDR 737175
IODOSORB Ointment	See MDR 737176
IODOSORB Powder	See MDR 733301
BACTIGRAS	See MDR 733299

Class IIb	Intended purpose
Polyurethane dressings (1)	Triple layer construction facilitates dynamic fluid management to provide a moist wound healing environment, which promotes healing and may help minimise the risk of maceration.
Polyurethane dressings (2)	Intended to facilitate high fluid management and promotes a moist wound healing environment which is optimal for healing. Intended for pressure ulcer prevention on intact skin, including pressure ulcers caused by medical devices, as part of a pressure ulcer prevention protocol.
Polyurethane dressings (3)	Intended to facilitate high fluid management and promote a moist wound healing environment which is optimal for healing, thereby helping to reduce the risk of maceration. Can be used for the prevention of medical device related pressure injuries on intact skin as part of a pressure injury protocol.

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Class IIb	Intended purpose
Polyurethane dressings (4)	Triple-layer construction facilitates high fluid handling capacity and promotes a moist wound healing environment which is optimal for healing.
Polyurethane dressings (5)	To provide a moist wound environment which is optimal for healing. To prevent pressure injury on intact skin as part of a pressure injury prevention protocol.
Polyurethane dressings (6)	Absorbent dressing with a waterproof top film which is permeable to moisture vapour to help promote a moist wound healing environment.
Alginate dressings	The presence of moisture, such as wound exudate causes dressing to gel, retaining excess fluid absorbed from the wound.
Hydrogel dressings (1)	Contain a hydrogel to promote gentle debridement through autolysis by rehydrating necrotic tissue. To promote a moist wound environment and conform easily to awkward wound shapes, which facilitates the packing of cavity wounds to allow them to heal from the base.
Hydrogel dressings (2)	To promote gentle debridement through autolysis by rehydrating necrotic tissue. To promote a moist wound environment and be non-adherent.
Gauze impregnated without antiseptic	Wound contact layers that protect the wound to support healing.
Non-adhesive absorbent dressings	Intended for exudate absorption and the management of wounds.
Single Use Negative Pressure Wound Therapy System	Indicated for patients who would benefit from a suction device (NPWT) as they may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

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Class IIb	Intended purpose
Cellulose and / or Modified Cellulose Dressings	This highly absorbent and conformable dressing is designed to rapidly form a clear gel on contact with wound fluid, minimising trauma to the wound and pain to the patient on removal. The dressing absorbs fluid and locks it away, providing a moist wound environment which may support autolytic debridement and conforms intimately to the wound bed. The high integral wet strength of the dressing facilitates easy one-piece removal from moist wound beds and cavity wounds.
Wound Contact Layer Dressings	Designed to act as a non-adherent interface between the wound and the secondary dressing, thus helping to protect the wound site from tissue disturbance during dressing changes.
Negative Pressure Wound Therapy Dressings and Accessories (1)	Indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials.
Negative Pressure Wound Therapy Dressings and Accessories (2)	Intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.
Elastic Compression Bandages (1)	Designed to apply sustained graduated compression for the management of venous leg ulcers and associated conditions.
Elastic Compression Bandages (2)	Designed to apply sustained graduated compression for the management of mixed aetiology leg ulcers.
Negative Pressure Wound Therapy Pumps	Indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

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Class IIb	Intended purpose
Hydrodissectors	Intended for wound debridement (acute, chronic wounds and burns), soft tissue debridement and cleansing of the surgical site in applications that, in the physician's judgement, require sharp debridement

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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
2021-09-07	3258304	Issued.
2022-01-13	3604563	Supplemented – Addition of device category Alginate wound dressings. Supplemented – Addition of device category Hydrogel dressings. Amended – Addition of legal manufacturer SRN. Amended – Addition of crucial supplier. Amended – Addition of critical subcontractor for sterilisation. Amended – Addition of 'Moist Heat Sterilisation' to the services provided by existing critical subcontractor.
2022-10-26	3658465	Amended – Correction of 'Class III Implantable' to 'Class III' in the scope table for Biobrane. Amended – Correction of Foam Wound Dressings with Silicone Adhesive to separate lines including 'with border' and 'without border'. Supplemented – Addition of Superabsorbent Wound Dressings with Silicone Adhesive devices (with border). Supplemented – Addition of Superabsorbent Wound Dressings with Silicone Adhesive devices (without border). Supplemented – Addition of Gauze impregnated without antiseptic devices. Amended – Addition of critical subcontractors for sterilisation.
2022-11-04	3772415	Supplemented – Addition of Durafiber Ag. Amended – Administrative update to the history.

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Date	Reference Number	Action
2023-01-05	3809641	Supplemented – Addition of Hydrocellular Foam Wound Dressings (with and without border). Supplemented – Addition of Polyurethane dressings. Supplemented – Addition of Non-adhesive absorbent dressings. Amended – Correction of wording for Foam Wound Dressings with Silicone Adhesive (with and without border) and Superabsorbent Wound Dressings with Silicone Adhesive (with and without border). Amended – Correction of date format to be as follow: YYYY-MM-DD.
2023-03-30	3768728	Supplemented – Addition of ALLEVYN Ag Adhesive Supplemented – Addition of ALLEVYN Ag Non-adhesive Supplemented – Addition of ALLEVYN Ag Gentle Border Supplemented – Addition of Single Use Negative Pressure Wound Therapy System
2023-06-05	30000467	Supplemented – Addition of Cellulose and / or Modified Cellulose Dressings Supplemented – Addition of Wound Contact Layer Dressings Amended – Addition of crucial supplier

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Date	Reference Number	Action
2023-09-06	30001440	Supplemented – Addition of Negative Pressure Wound Therapy Dressing and Accessories Supplemented – Addition of Elastic Compression Bandages Amended – Grouping of Hydrocellular Foam Wound Dressings (with and without border), Foam Wound Dressings with Silicone Adhesive (With and without border), Superabsorbent Wound Dressings with Silicone Adhesive (With and without border), Polyurethane foam and Polyurethane dressings under Polyurethane dressings with updated intended purpose Amended – Name change of Alginate wound dressings to Alginate dressings Amended – Addition of critical subcontractors for manufacture Amended – Addition of critical subcontractors for ETO sterilisation
2023-10-16	30008438	Supplemented – Addition of Negative Pressure Wound Therapy Pumps Amended – Addition of critical subcontractor for software development Amended – Addition of critical subcontractor for manufacture
2023-11-17	30016128	Supplemented – Addition of Acticoat Flex 3 Supplemented – Addition of Acticoat Flex 7 Amended – Addition of critical subcontractors for manufacture and supply of finished devices Amended – Addition of crucial supplier of medicinal substance

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Date	Reference Number	Action
2024-01-17	30060735	Supplemented – Addition of ACTICOAT/ARGENCOAT Supplemented – Addition of ACTICOAT 7
2024-04-10	30115984	Supplemented – Addition of IODOSORB Ointment Supplemented – Addition of IODOSORB Dressing Amended – Addition of critical subcontractor for manufacture Amended – Addition of critical subcontractor for sterilisation Amended – Addition of crucial suppliers of iodine
2024-06-24	30169500	Supplemented – Addition of IODOSORB Powder Supplemented – Addition of BACTIGRAS Amended – Addition of critical suppliers for BACTIGRAS
2024-12-17	30310756	Amended – Addition of critical subcontractors for manufacture
2025-04-10	30424896	Amended – Re-addition of ACTICOAT/ARGENCOAT and ACTICOAT 7 in device schedule table as this was omitted in error from previous certificate updates (first omission: SMO 30115984)
2026-02-17	30561053	Amended – Update of intended purpose for all class IIb devices to align with IFUs Amended – Addition of subgroups in the form of a number after the group name to differentiate the different intended purposes for devices contained within a same group

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Date	Reference Number	Action
2026-07-28	30762280	Supplemented – Qualification of Parametric Release for devices belonging to generic device groups Polyurethane dressings and Single Use Negative Pressure Wound Therapy System at existing EtO sterilisation subcontractor Supplemented – Addition of sterilisation cycle for devices belonging to generic device group Single Use Negative Pressure Wound Therapy System at existing EtO sterilisation subcontractor Supplemented – Addition of subcontractor for EtO sterilisation of Single Use Negative Pressure Wound Therapy System and Polyurethane dressings
Current	30729465	Re-issued – Certificate renewal Re-issued – Addition of hydrodissectors

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