bsi.

By Royal Charter

EU Quality Management System Certificate

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

MDR 738968 R000

Manufacturer: ConvaTec Limited

Address:
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

Single Registration Number: GB-MF-000001770

EU Authorised Representative: Unomedical A/S

Address:
Aaholmvej 1-3, Osted
4320 Lejre
Denmark

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: **2021-11-10**

Current Issue Date: **2025-11-11**

Starting Validity Date: **2025-11-11**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Hydrofiber burn dressing with silver	See MDR 739175
Foam and hydrofiber dressing with silver (adhesive and non adhesive)	See MDR 739169
Hydrofiber dressing with silver, ETDA & BEC	See MDR 739171
Hydrofiber ribbon dressing with silver, ETDA & BEC	See MDR 739173
Hydrofiber surgical cover dressing with silver	See MDR 739159
Hydrofiber surgical cover dressing	See MDR 747389
Hydrocolloid dressing – extra thin	See MDR 766308
Hydrocolloid dressing – CGF (border and non-border)	See MDR 766310
Hydrocolloid dressing - Signal	See MDR 766311
Wound dressing – nitric oxide generating	See MDR 791766
Collagen wound matrix dressing	See MDR 821626

Class IIb	Intended purpose
Foam and hydrofiber dressing (adhesive and non-adhesive)	Treatment of leg ulcers, pressure sores, diabetic foot ulcers, surgical wounds, partial thickness burns and traumatic wounds Protection of intact skin against breakdown
Silicone foam and hydrofiber dressing	Treatment of leg ulcers, pressure sores, diabetic foot ulcers, surgical wounds and traumatic wounds Protection of intact skin against breakdown
Silicone foam - lite	Management of low to non-exuding wounds: Leg ulcers, pressure ulcers and diabetic ulcers; surgical wounds (e.g. post-operative wounds left to heal by secondary intent and donor sites); partial thickness (second degree) burns; traumatic wounds (e.g. abrasions, lacerations, blisters, minor cuts and skin tears)

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Class IIb	Intended purpose
Negative pressure wound therapy dressing	Indicated for patients with a low to moderately exuding wound that would benefit from a NPWT device such as surgically closed incision sites, venous leg ulcers, diabetic ulcers, pressure ulcers, dehisced wounds, flaps and grafts and traumatic wounds
Hydrofiber dressing (1)	Indicated for leg ulcers including venous ulcers and arterial ulcers, diabetic ulcers, pressure ulcers/injuries, surgical, traumatic and partial thickness burns
Hydrofiber ribbon dressing with strengthening fibres	Indicated for diabetic foot ulcers, pressure ulcers/injuries, surgical wounds, traumatic wounds
Hydrofiber dressing (2)	Indicated for leg ulcers including venous ulcers and arterial ulcers, diabetic ulcers, pressure ulcers/injuries, surgical, traumatic and malignant wounds
Alginate dressing	For the management of moderate to heavily exuding wounds. Indicated for pressure ulcers, venous leg ulcers, arterial leg ulcers, mixed aetiology ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, bleeding wounds and skin graft donor sites
Activated charcoal dressing	For the management of malodorous wounds Indicated for pressure ulcers, arterial leg ulcers, venous leg ulcers, mixed aetiology ulcers and diabetic foot ulcers
Hydrogel and applicator nozzle	Intended to be used as a primary dressing or wound filler. Indicated for arterial, venous and mixed aetiology leg ulcers and pressure injury/ulcers.

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

Device(s)	Risk Classification
Negative pressure wound therapy pump	Class IIa
Faecal management system	Class IIa
Loop ostomy rods	Class IIa
Intermittent urinary catheters	Class Is
Adhesive remover spray sting free	Class Is
Skin barrier foam applicator sting free	Class Is
Hydrocolloid sealing strips	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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