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: **2024-05-30**

Starting Validity Date: **2024-05-30**

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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 dressing with silver	See MDR 739152
Hydrofiber ribbon dressing with silver & strengthening fibres	See MDR 739152
Hydrofiber Extra dressing with silver	See MDR 739160
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

Class IIb	
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	
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 and venous leg ulcers
Hydrofiber dressing	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 Extra dressing	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

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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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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
2021-11-10	3327824	Issued
2022-01-26	3586985	Supplemented – addition of device categories: Hydrofiber burn dressing with silver, Foam and hydrofiber dressing, Silicone foam and hydrofiber dressing, Silicone foam lite Amended – addition of subcontractors for manufacture and sterilization and addition of Radiation (x-ray sterilization) to services supplied for subcontractor
2022-03-16	3625126	Supplemented – addition of foam and hydrofiber dressings with silver Supplemented – addition of adhesive remover sting free Supplemented – addition of skin barrier foam applicator sting free Amended – addition subcontractors for manufacture and administrative change to subcontractor name
2022-04-06	3662345	Supplemented – addition of Hydrofiber & Hydrofiber ribbon dressing with silver, ETDA & BEC Amended – addition of subcontractor for sterilization
2022-06-21	3700515	Supplemented – addition of Hydrofiber dressing with silver, Hydrofiber ribbon dressing with silver & strengthening fibre and Hydrofiber Extra with silver
2022-07-28	3728630	Supplemented: addition of Hydrofiber surgical cover dressing with silver Amended – addition of subcontractors for manufacture and sterilization
2022-09-06	3734044	Supplemented: addition of Hydrofiber surgical cover dressing, NPWT dressing and NPWT pump

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Date	Reference Number	Action
2022-11-23	3785834	Supplemented – addition of Hydrofiber dressing, Hydrofiber ribbon dressing with strengthening fibres, Hydrofiber Extra dressing and Hydrocolloid sealing strips Amended – administrative update to previous history entries 3586985, 3625126, 3662345, 3728630
2023-07-07	30000499	Supplemented – addition of faecal management system and addition of venous leg ulcer to intended purpose for NPWT dressing Amended – addition of subcontractor for manufacture for faecal management system and subcontractor for radiation (gamma sterilization) for number of devices
2023-10-24	30003207	Supplemented – addition of hydrocolloid dressing – extra thin, alginate dressing and loop ostomy rods Amended – addition of critical subcontractor for manufacture & assembly for loop ostomy rods
2023-11-14	30051461	Amended – addition of subcontractor for manufacture for intermittent catheters Amended – addition of two subcontractors for ETO sterilization for intermittent catheters
2023-12-19	30060429	Supplemented – addition of Hydrocolloid dressing – CGF (border and non-border), Hydrocolloid dressings – Signal and Activated charcoal dressing
2024-04-05	30128352	Amended – addition of critical subcontractor for manufacture and packaging of intermittent catheters
Current	30183901	Amended – addition of critical subcontractor for ETO sterilisation for Class IIb foam dressings & addition of two critical subcontractors for manufacture of Class IIb foam dressings Amended – correction to intended purpose for silicone and hydrofiber dressing

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