By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 739171 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2022-04-06**

Current Issue Date: **2024-12-19**

Starting Validity Date: **2024-12-19**

Expiry Date: **2027-04-05**

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Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Aquacel Ag+ Extra dressing					
Aquacel Ag+ Extra with silver, EDTA and BEC dressing with strengthening fiber	413566	MDN 1204	For wound that are infected or at risk of infection Indicated for Leg ulcers, including: • Venous stasis ulcers • Arterial ulcers • Leg ulcers of mixed aetiology Diabetic foot ulcers Pressure ulcers/injuries Surgical wounds Traumatic wounds Malignant wounds Partial thickness burns	Class III	768455AWC00113B
	413567				
	413568				
	413569				
	413577				
	413583				
	413580				
	413581				
	413598				
	413599				

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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
2022-04-06	3324575	Issued
2024-01-22	30006880	Amended – change to primary packaging sealing parameters
2024-05-31	30073636	Amended – change of crucial supplier site
2024-11-21	30248064	Amended – change to shelf life
Current	30294422	Amended – change to benzethonium chloride specification limit

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