EU Technical Documentation Assessment Certificate

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

MDR 739173 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 Medical Devices

First Issued: **2022-04-06** Date: **2022-04-06** 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+ ribbon dressing					
Aquacel Ag+ ribbon with silver, EDTA and BEC dressing with strengthening fiber	413570 413571 413572	MDN 1204	For wounds 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	Class III	768455AWC00243L

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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
Current	3324579	Issued

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