

# 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

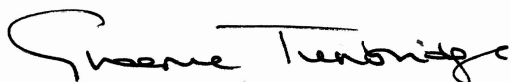
**Address:**

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: **2025-11-26**

Starting Validity Date: **2025-11-26**

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

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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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
<b>Aquacel Ag+ Extra dressing &amp; Aquacel Ag Advantage</b>					
Aquacel Ag+ Extra with silver, EDTA and BEC dressing with strengthening fiber & Aquacel Ag Advantage with silver, EDTA and BEC	413566	MDN 1204	For wound that are infected or at risk of infection  Indicated for Leg ulcers, including: <ul style="list-style-type: none"> <li>• Venous stasis ulcers</li> <li>• Arterial ulcers</li> <li>• Leg ulcers of mixed aetiology</li> </ul> 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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