

EU Technical Documentation Assessment Certificate

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

MDR 739169 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

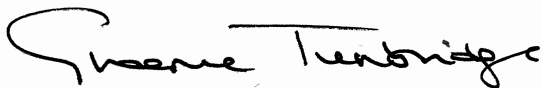
Address:

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: **2022-03-16**

Date: **2022-03-16**

Expiry Date: **2027-03-15**

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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 Foam Adhesive Dressing	420627	MDN 1204	Primary dressing for the management of exuding acute and chronic wounds which are at risk of infection or show signs of infection.	Class III	768455AWC00123D
	420628				
	420629				
	420647				
	420648				
	420649				
	420681				
	420805				
	420807				
Aquacel Ag Foam Dressing	421491	MDN 1204	Primary dressing for the management of exuding acute and chronic wounds which are at risk of infection or show signs of infection.	Class III	768455AWC00123D
	420639				
	420642				
	420644				
	420645				
	420646				
	420806				

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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	3324569	Issued



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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.