

# EU Technical Documentation Assessment Certificate

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

## MDR 739152 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

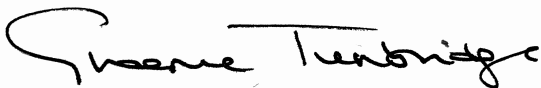
**Address:**

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: **2022-06-21**

Date: **2022-06-21**

Expiry Date: **2027-06-20**

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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 dressing                        | 403739 | MDN 1204                           | Indicated for:<br>Partial thickness burns<br>Leg ulcers, including:<br>• Venous stasis ulcers<br>• Arterial ulcers<br>• Leg ulcers of mixed aetiology<br>Diabetic foot ulcers<br>Pressure ulcers/injuries<br>Surgical wounds<br>Traumatic wounds  | Class III           | 768455AWC00253N |
|  | 403740 |                                    |   |                     |                 |
|  | 403741 |                                    |   |                     |                 |
|  | 403705 |                                    |   |                     |                 |
|  | 403706 |                                    |   |                     |                 |
|  | 403707 |                                    |   |                     |                 |
|  | 403708 |                                    |   |                     |                 |
|  | 403722 |                                    |   |                     |                 |
|  | 403723 |                                    |   |                     |                 |
|  | 403709 |                                    |   |                     |                 |
|  | 403710 |                                    |   |                     |                 |
|  | 403720 |                                    |   |                     |                 |
| 403711                                     |        |                                    |   |                     |                 |
| Aquacel Ag ribbon with strengthening fibre | 403771 | MDN 1204                           | Indicated for:<br>Wounds where there is an infection or an increased risk of infection<br>Leg ulcers, including:<br>• Venous stasis ulcers<br>• Arterial ulcers<br>• Leg ulcers of mixed aetiology<br>Diabetic foot ulcers<br>Pressure ulcers/injuries<br>Surgical wounds<br>Traumatic wounds | Class III           | 768455AWC00253N |
|  | 403773 |                                    |   |                     |                 |
|  | 420128 |                                    |   |                     |                 |

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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 | 3324457          | 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.