

EU Declaration of Conformity

[Aquacel Ag Burn Dressing] – [Sterile]

(Technical Documentation MDR [AWCDD-009])

We hereby declare;

- that the listed product/s comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745 and any other applicable European Union legislation
- that this EU declaration of conformity is issued under the sole responsibility of ConvaTec.

Legal Manufacturer: ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU, United Kingdom

Single Reg # (SRN): GB-MF-000001770

Authorized Representative: Unomedical a/s, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark

Product Name: AQUACEL Ag Burn

Intended Purpose AQUACEL Ag BURN dressing is intended to be used in the management of burns.

Basic UDI-DI: 768455AWC00043E

GMDN Code & Name: 47474, Exudate absorbent dressing, hydrophilic – gel, antimicrobial, sterile

EMDN Code & Description: M040408 Dressings, Silver

Device(s) & Cat. #: Refer to Appendix A

Risk Class: Class III as per Rules 4 and 14 in Annex VIII

Common N/A

Specifications (CS):

Notified Body: BSI Group The Netherlands B.V., Notified Body Number 2797, Say Building, John.M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Certificate(s): EC Quality Management System Certificate No. CE MDR 738968, issued by BSI Notified Body Number 2797 in accordance with Annex IX Chapter I & III of this Regulation
EC Technical Documentation Assessment Certificate No. CE MDR 739175, issued by BSI Notified Body Number 2797 in accordance with Annex IX chapter II of this Regulation

**Legal Manufacturer
authorized
signature:**

Signature:

Signed by:
Steeve Lamvohee
 Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Oct 20, 2025 | 10:47:42 AM BST
79126EF62CD04B7AA0479B4D5AA7AE9 **Date:** Oct 20, 2025
Steeve Lamvohee
Head of IC/AWC Regulatory Affairs
Place of Issue: Deeside, Flintshire

Appendix A: Products

ICC CODE	SAP code	Size/Pack Size	Dressings/carton
403786	1263655	13cm x 10cm Flat Dressing - EUR	5 Dressings per Carton
403787	1263658	17cm x 15cm Flat Dressing - EUR	5 Dressings per Carton
403788	1263527	23cm x 30cm Flat Dressing - EUR	5 Dressings per Carton
403789	1263528	23cm x 100cm Flat Dressing - EUR	3 Dressings per Carton
403790	1263529	54cm x 45cm Flat Dressing – EUR	3 Dressings per Carton