	Effective Date:	25-Nov-2024		
	Status:	Effective	Version:	5.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	Title:	Declaration of Conformity Form		

[EU] Declaration of Conformity

Aquacel Ag Foam Dressing – Sterile

Technical Documentation MDR [AWCDD-005]

Issued by: ConvaTec

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

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

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

Actor ID/SRN: DK-AR-000000941

Product Name: Aquacel Ag Foam Adhesive; Aquacel Ag Foam Non Adhesive

Intended Purpose Aquacel Ag Foam dressings have been designed to be used as a primary dressing. Aquacel Ag Foam dressings may be used with the direction of a healthcare professional, for the management of exuding acute and chronic wounds which are at risk of infection or show signs of infection.

Basic UDI-DI: 768455AWC00123D

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

Notified Body: BSI 2797

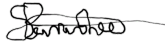
Certificate(s): EU Quality Management System Certificate (Regulation (EU) 2017/745, Annex IX Chapter I and III)
MDR #: 738968 R000, first Issued by BSI (2021-11-10)
EU Technical documentation assessment certificate (Regulation (EU) 2017/745, Annex IX Chapter II)
MDR # : 739169 R000, first Issued by BSI (2022-03-16)

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**Legal Manufacturer
authorized signature:**

Signature:

Signed by:



Date: Sep 15, 2025



Signer Name: steeve
 Signing Reason: I approve this document
 Signing Time: Sep 15, 2025 | 11:28:17 AM BST
 79126EF62CD04B7AA0479B4D5AA7AE98

Name: Steve Lamvohee
Title: Head of IC/AWC Regulatory Affairs
Place of Issue: Deeside, Flintshire

Appendix A: Products

ICC	SAP	Description
420647	1703977	AQUACEL FOAM AG ADH HEEL(1X5) CEE
420647	1703975	AQUACEL FOAM AG ADH HEEL(1X5) EUR
420627	1703962	AQUACEL FOAM AG ADH 12.5X12.5 (1X10) EUR
420627	1703964	AQUACEL FOAM AG ADH 12.5X12.5 (1X10) CEE
420628	1703966	AQUACEL FOAM AG ADH 17.5X17.5 (1X10) EUR
420628	1703968	AQUACEL FOAM AG ADH 17.5X17.5 (1X10) CEE
420629	1703971	AQUACEL FOAM AG ADH 21X21 (1X5) EUR
420629	1703973	AQUACEL FOAM AG ADH 21X21 (1X5) CEE
420648	1703979	AQUACEL FOAM AG ADH SACRAL 20X16.9 (1X5) EUR
420648	1703981	AQUACEL FOAM AG ADH SACRAL 20X16.9 (1X5) CEE
420649	1703961	AQUACEL FOAM AG ADH 12.5X12.5 (1X3) ES
420681	1705404	AQUACEL FOAM AG ADH 10X10 (1x10) EUR
420681	1705405	AQUACEL FOAM AG ADH 10X10 (1x10) CEE
420805	1707750	AQUACEL FOAM AG ADH 8X8 (1X10) CEE
420805	1707749	AQUACEL FOAM AG ADH 8X8 (1X10) EUR
420807	1707758	AQUACEL FOAM AG ADH 25X30 (1X5) EUR
420807	1707759	AQUACEL FOAM AG ADH 25X30 (1X5) CEE
421491	1713242	AQUACEL FOAM AG ADH SACRAL 20X16.9 (1X3) ES
420639	1704010	AQUACEL FOAM AG N/ADH 5X5 (1X10) CEE
420639	1704008	AQUACEL FOAM AG N/ADH 5X5 (1X10) EUR
423985	1749515	AQUACEL FOAM AG N/ADH 10X10 1X3 STER ES
420642	1704014	AQUACEL FOAM AG N/ADH 10X10 (1X10) EUR
420642	1704016	AQUACEL FOAM AG N/ADH 10X10 (1X10) CEE
420644	1704019	AQUACEL FOAM AG N/ADH 15X15 (1X3) ES
420645	1704020	AQUACEL FOAM AG N/ADH 15X15 (1X5) EUR
420645	1704022	AQUACEL FOAM AG N/ADH 15X15 (1X5) CEE
420646	1704026	AQUACEL FOAM AG N/ADH 20X20 (1X5) CEE
420646	1704024	AQUACEL FOAM AG N/ADH 20X20 (1X5) EUR
420806	1707754	AQUACEL FOAM AG N/ADH 15X20 (1X5) EUR
420806	1707755	AQUACEL FOAM AG N/ADH 15X20 (1X5) CEE