convatec – forever caring –	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 WSF Ribbon Dressing

Aquacel Extra Dressing

Technical Documentation MDR [AWC-TF-022]

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 WSF RIBBON Dressing Aquacel EXTRA Dressing
Intended Purpose	Aquacel WSF Ribbon Dressings have been designed to be used as a primary dressing for cavity wounds. They are intended to be used under the direction of a healthcare professional as per the indications for use. Aquacel Extra Dressings have been designed to be used as a primary dressing under the direction of a healthcare professional as per the indications for use.
Basic UDI-DI:	768455AWC00213E
GMDN Code & Name:	43186, Exudate-absorbent dressing, hydrophilic-gel, non-antimicrobial
EMDN Code & Description:	M040404 Cellulose and/or Modified Cellulose Dressings, Non-Combined or Combined with other Substances
Device(s) & Cat. #:	Refer to Appendix A
Risk Class:	Class IIb (MDR 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, Issued by BSI (First issue date: 2021-11-10)

Legal Manufacturer authorized signature:

Signature: Signed by: Steeve Lamvohee
Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Nov 21, 2025 | 4:25:00 PM GMT
79126EF62CD04B7AA0479B4D5AA7AE98

Date: Nov 21, 2025

Name: Steeve Lamvohee
Title: Head of IC/AWC RegulatoryAffairs
Place of Issue: Deeside, Flintshire

Appendix A: Products

SAP	ICC	Description	UDI-DI
Aquacel EXTRA Dressing			
1704589	420671	Aquacel EXTRA 5X5CM (1X10PK) STER NAI	00768455125586
1704591	420671	Aquacel EXTRA 5X5CM (1X10PK) STER CEE	00768455125586
1730132	420671	Aquacel EXTRA 5X5CM (1X10PK) STER DE	00768455170616
1704590	420671	Aquacel EXTRA 5X5CM (1X10PK) STER EUR	00768455125609
1704593	420672	Aquacel EXTRA 10X10CM (1X10PK) STER EUR	00768455125616
1704694	420672	Aquacel EXTRA 10X10CM (1X10PK) STER CEE	00768455125616
1730131	420672	Aquacel EXTRA 10X10CM 1X10PK STER DE	00768455170609
1704596	420673	Aquacel EXTRA 15X15CM (1X5PK) STER EUR	00768455125630
1704597	420673	Aquacel EXTRA 15X15CM (1X5PK) STER CEE	00768455125630
1730130	420673	Aquacel EXTRA 15X15CM 1X5PK STER DE	00768455170593
1708221	420814	Aquacel EXTRA 10X10CM (1X5PK) STER EUR	00768455125616
1708222	420815	Aquacel EXTRA 10X10CM (1X3PK) BE/NL/LU	00768455125616
1708223	420815	Aquacel EXTRA 10X10CM (1X3PK) STER ES	00768455125616
1708224	420816	Aquacel EXTRA 5X5CM (1X3PK) STER ES	00768455125586
1708225	420816	Aquacel EXTRA 5X5CM (1X3PK) STER BE/NL/LU	00768455130504
1708226	420817	Aquacel EXTRA 15X15CM (1X3PK) BE/NL/LU	00768455125630
1708227	420817	Aquacel EXTRA 15X15CM(1X3PK) STER ES	00768455125630
1708230	420820	Aquacel EXTRA 4X10CM (1X10PK) STER EUR	00768455130443
1708231	420821	Aquacel EXTRA 4X20CM (1X10PK) STER EUR	00768455130450
1708232	420822	Aquacel EXTRA 4X30CM (1X10PK) STER EUR	00768455130467
1708235	420825	Aquacel EXTRA 5X10CM (1X10PK) STER CEE	00768455130375
1729778	422622	Aquacel EXTRA 20X24CM (1X10PK) STER FR	00768455170470
1729907	422627	Aquacel EXTRA 12.5X12.5CM 1X10PKSTER EUR	00768455130382
1734011	423409	Aquacel EXTRA 20 X 24CM (1X5PK) STER EUR	00768455170470
1708237	420826	Aquacel EXTRA 13.5X15CM 1X10PK STER EUR	00768455170470
1738379	423785	Aquacel Extra 7X10CM (1X10PK) STER FR	00768455208968
1738380	423787	Aquacel Extra 15X15CM (1X10PK) STER FR	00768455208975

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Aquacel WSF RIBBON Dressing			
1729903	422624	Aquacel WSF 2.5X40CM (1X10PK) STER EUR	00768455195930
1247642	403770	Aquacel WSF 2X45CM (1X5PK) STER EUR	00768455106752
1247674	403770	Aquacel WSF 2X45CM STER (1X5PK) STER CEE	00768455106769
1700178	420127	Aquacel WSF 1X45CM (1X5PK) STER EUR	00768455118229
1247668	403772	Aquacel WSF 2.5X40CM (1X16PK) STER EUR	00768455195930
1738381	423786	Aquacel WSF 2.5X48CM (1X10PK) STER FR	00768455208982

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Revision History

Rev No	Date	Comment	Author
1	05/01/2024	Initial issue of Declaration of conformity under EU Medical Device Regulation (EU) 2017/745 (French Reimbursement WSF code only ICC 423786) in line with TW#1563757.	Maryam Etemad
2	08/03/2024	Technical File Update	Maryam Etemad
3	19/09/2024	Technical File Update ,removal of ICC code 403774 -	Maryam Etemad
4	11/09/2025	Technical file update, removal of Aquacel from scope as discontinued under MDR.	Adam Brine
5	17/11/2025	Technical file update – correction of minor errors in product code descriptions, addition of missed product codes: (SAP: 1708225, ICC: 420816), (SAP: 1704590, ICC: 420671)	Adam Brine

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