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|  | 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:

 Signer Name: Steeve Lamvohee
 Signing Reason: I approve this document
 Signing Time: Nov 21, 2025 14:25:00 PM GMT
 79126EF62CD04B7AA0479B4D5AA7AE98


Date: Nov 21, 2025

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

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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 |