

[EU] Declaration of Conformity

[Aquacel Ag+ Extra & Aquacel Ag+ Ribbon WSF]-[Sterile]

(Technical Documentation /MDR [AWCDD-011])

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

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

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

Product Name: AQUACEL Ag+ EXTRA
AQUACEL Ag+ WSF Ribbon

Intended Purpose Aquacel Ag+ EXTRA™ Dressings have been designed to be used as a primary dressing. They are intended to be used under the direction of a healthcare professional for wounds, which are at risk of infection or show signs of infection, or where biofilm is suspected to be present, and in accordance with the indications for use.

Aquacel™ Ag+ Ribbon Dressings have been designed to be used as a primary dressing for cavity wounds. They are intended to be used with the direction of a healthcare professional for wounds, which are at risk of infection or show signs of infection, or where biofilm is suspected to be present, and in accordance with the indications for use.

Basic UDI-DI: AQUACEL Ag+ EXTRA: 768455AWC00113B
AQUACEL Ag+ WSF Ribbon: 768455AWC00243L

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 Specifications (CS): N/A

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

For AQUACEL Ag+ EXTRA, EC Technical Documentation Assessment Certificate No. CE MDR 739171, issued by BSI Notified Body Number 2797 in accordance with Annex IX chapter II of this Regulation

For AQUACEL Ag+ WSF Ribbon, EC Technical Documentation Assessment Certificate No. CE MDR 739173, issued by BSI Notified Body Number 2797 in accordance with Annex IX chapter II of this Regulation

**Legal Manufacturer
authorized
signature:**

Signature:

DocuSigned by:



Signer Name: Steeve Lamvohee

Signing Reason: I approve this document

Signing Time: Jul 8, 2024 | 9:16:26 PM BST

Date: Jul 8, 2024

79126EF62CD04B7AA0479B4D5AA7AE98
Steeve Lamvohee

Head of IC/AWC Regulatory Affairs

Place of Issue: Deeside, Flintshire

Appendix A: Products

AQUACEL Ag+ EXTRA Dressings:

ICC	SAP	Description
413566	1708330	AQUACEL Ag+ EXTRA 5x5cm
413567	1708331	AQUACEL Ag+ EXTRA 10x10cm
413568	1708334	AQUACEL Ag+ EXTRA 15x15cm
413569	1708335	AQUACEL Ag+ EXTRA 20x30cm
413577	1708347	AQUACEL Ag+ EXTRA 10x13cm
413583	1708350	AQUACEL Ag+ EXTRA 15x14.5cm
413580	1708358	AQUACEL Ag+ EXTRA 5x6cm
413581	1708359	AQUACEL Ag+ EXTRA 4x10cm
413598	1708360	AQUACEL Ag+ EXTRA 4x20cm
413599	1708361	AQUACEL Ag+ EXTRA 4x30cm
413566	1708962	AQUACEL Ag+ EXTRA 5x5cm CEE
413567	1708963	AQUACEL Ag+ EXTRA 10x10cm CEE
413568	1708964	AQUACEL Ag+ EXTRA 15x15cm CEE
413569	1708965	AQUACEL Ag+ EXTRA 20x30cm CEE
413567	1730137	AQUACEL Ag+ EXTRA 10x10cm DE
413566	1743534	AQUACEL Ag+ EXTRA 5x5cm DE
413568	1743535	AQUACEL Ag+ EXTRA 15x15cm DE
413569	1743536	AQUACEL Ag+ EXTRA 20x30cm DE

AQUACEL Ag+ WSF Ribbon Dressings:

ICC	SAP	Description
413570	1708336	AQUACEL Ag+ WSF Ribbon 1x45cm
413571	1708337	AQUACEL Ag+ WSF Ribbon 2x45cm
413571	1708967	AQUACEL Ag+ WSF Ribbon 2X45cm CEE
413572	1708362	AQUACEL Ag+ WSF Ribbon 2.5x45cm ES
413570	1743537	AQUACEL Ag+ WSF Ribbon 1x45cm DE
413571	1743538	AQUACEL Ag+ WSF Ribbon 2x45cm DE

Revision History

Rev No	Date	Comment	Author																		
1	31/01/2023	Initial issue of Declaration of conformity under EU Medical Device Regulation (EU) 2017/745	Ashley Stratton-Powell																		
2	02/03/2023	Technical documentation updated to demonstrate compliance to The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended).	Ashley Stratton-Powell																		
3	24/08/2023	<div>Addition of the following Aquacel Ag+ Extra & WSF new codes for DACH region as part of TW#1602301.</div> <div>SAP Codes added:</div> <table><tr><th>Product Description</th><th>*ICC Code (Model Number)</th><th>SAP Code (Finished Product Code)</th></tr><tr><td>CTN AQUACEL AG+ EXTRA 5X5CM 1X10PK DE</td><td>413566</td><td>1743534</td></tr><tr><td>CTN AQUACEL AG+ EXTRA 15X15CM 1X5PK DE</td><td>413568</td><td>1743535</td></tr><tr><td>CTN AQUACEL AG+ EXTRA 20X30CM 1X5PK DE</td><td>413569</td><td>1743536</td></tr><tr><td>CTN AQUACEL AG+ WSF 1X45CM 1X5PK DE</td><td>413570</td><td>1743537</td></tr><tr><td>CTN AQUACEL AG+ WSF 2X45CM 1X5PK DE</td><td>413571</td><td>1743538</td></tr></table>	Product Description	*ICC Code (Model Number)	SAP Code (Finished Product Code)	CTN AQUACEL AG+ EXTRA 5X5CM 1X10PK DE	413566	1743534	CTN AQUACEL AG+ EXTRA 15X15CM 1X5PK DE	413568	1743535	CTN AQUACEL AG+ EXTRA 20X30CM 1X5PK DE	413569	1743536	CTN AQUACEL AG+ WSF 1X45CM 1X5PK DE	413570	1743537	CTN AQUACEL AG+ WSF 2X45CM 1X5PK DE	413571	1743538	Rebecca Davies
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4	05/07/2024	<div>CCRs incorporated into the technical file:</div> <div><ul style="list-style-type: none">• TW1608918 Bioburden limit spec format change• TW1760809 Doyen 1 Vision System• TW1689327 Capacity increase for Textile Line TL4• TW1575607 Silver Nitrate Solution Blending site Change• TW1578763 Sodium Hydroxide 27% solution blending change</div> <div>Regular technical file updates.</div>	Maryam Etemad																		