

[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

Actor ID/SRN: DK-AR-000000941

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:

Signed by:

 Signer Name: Steeve Lamvohee
 Signing Reason: I approve this document
 Signing Time: May 27, 2025 | 11:42:22 AM BST
 79126EF62CD04B7AA0479B4D5AA7AE98

May 27, 2025

Date:

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

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 739173 R000

Manufacturer: ConvaTec Limited

Address:

First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

Single Registration Number: GB-MF-000001770

EU Authorised Representative: Unomedical A/S

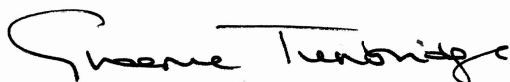
Address:

Aaholmvej 1-3, Osted
4320 Lejre
Denmark

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-04-06**

Current Issue Date: **2025-11-26**

Starting Validity Date: **2025-11-26**

Expiry Date: **2027-04-05**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 739173 R000

Device Schedule:

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Aquacel Ag+ ribbon dressing & Aquacel Ag Advantage					
Aquacel Ag+ ribbon with silver, EDTA and BEC dressing with strengthening fiber & Aquacel Ag Advantage with silver, EDTA and BEC	413570	MDN 1204	For wounds that are infected or at risk of infection Indicated for Leg ulcers, including: <ul style="list-style-type: none"> • Venous stasis ulcers • Arterial ulcers • Leg ulcers of mixed aetiology Diabetic foot ulcers Pressure ulcers/injuries Surgical wounds Traumatic wounds Malignant wounds	Class III	768455AWC00243L
	413571				
	413572				

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.