	Approved Date:	12-Apr-2022		
	Status:	Approved	Version:	2.0
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
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EU Declaration of Conformity

AQUACEL Ag+ Extra (PR20-291) & AQUACEL Ag+ WSF Ribbon (PR20-292) **MDR-AWCDD-011**


This Declaration of Conformity is issued under the sole responsibility of ConvaTec Limited



We hereby declare that the mentioned product/ attached list of products comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745


Legal Manufacturer:	ConvaTec Limited First Avenue, Deeside Industrial Park, Deeside, Flintshire. CH5 2NU United Kingdom
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
GMDN Code and Term Name:	47474, Exudate absorbent dressing, hydrophilic – gel, antimicrobial, sterile
EMDN Code and Term Description:	M040408 Dressings, Silver
CND Code and Title:	M040408 Silver Dressings
Basic UDI-DI:	AQUACEL Ag+ EXTRA: 768455AWC00113B AQUACEL Ag+ WSF Ribbon:768455AWC00243L
Identification of the device(s) concerned:	Refer to Appendix A
Catalogue Number:	Refer to Appendix A
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

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	<p>infection or show signs of infection, or where biofilm is suspected to be present, and in accordance with the indications for use.</p> <p>AQUACEL Ag+ 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 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.</p>
Risk Classification:	Class III as per Rule 4 and 14 in Annex VIII
Conformity Assessment Route:	Annex I and Annex IX of EU Medical Device Regulation (EU) 2017/745
Relevant Harmonised Standards:	<p>EN ISO 13485: 2016</p> <p>EN ISO 14971: 2019</p> <p>EN ISO 15223-1: 2021</p> <p>EN ISO 11137-1:2015</p> <p>EN ISO 11737-1:2018</p> <p>EN ISO 11737-2:2020</p>
References to any CS:	N/A
Identification of Notified Body:	<p>BSI Group The Netherlands B.V.</p> <p>Notified Body Number 2797</p> <p>Say Building</p> <p>John.M. Keynesplein 9</p> <p>1066 EP Amsterdam</p> <p>Netherlands</p>
Identification of the Certificate(s):	<p>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</p>
	<p>For AQUACEL Ag+ EXTRA, EC Technical Documentation Assessment Certificate No. MDR 739171, issued by BSI.</p> <p>For AQUACEL Ag+ WSF Ribbon, EC Technical Documentation Assessment Certificate No. MDR 739173, issued by BSI.</p>

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<p>Identification of the person authorized to sign on behalf of Legal Manufacturer:</p>	<p>Name:</p> <p>Steeve Lamvohee</p> <p>Signature:</p> <p>DocuSigned by:</p>  <p> Signer Name: Steeve Lamvohee Signing Reason: I approve this document Signing Time: Aug 25, 2023 8:52:32 AM BST 79126EF62CD04B7AA0479B4D5AA7AE98</p> <p>Head of IC/ AWC Regulatory Affairs</p> <p>Place of Issue: Deeside, Flintshire</p> <p>Date: Aug 25, 2023</p>
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Appendix A: List of Product Range Covered under this Declaration of Conformity

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

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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><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></div>	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
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																			
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Trade/Brand Names for the Czech Republic

413571	AQUACEL Ag+
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