	Approved Date:	12-Apr-2022		
	Status:	Approved	Version:	2.0
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	Title:	WI-0506 Declaration of Conformity Form		


EU Declaration of Conformity



AQUACEL Ag Foam Adhesive (PR20-295) & AQUACEL Ag Foam Non-adhesive (PR20-298) MDR-AWCDD-005


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 Foam Adhesive AQUACEL Ag Foam Non-Adhesive
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:	768455AWC00123D
Identification of the device(s) concerned:	Refer to Appendix A
Catalogue Number:	Refer to Appendix A
Intended Purpose:	AQUACEL Ag Foam dressings have been designed to be used as a primary dressing. AQUACEL Ag Foam dressings may be used with the direction of a healthcare professional, for the management of exuding acute and chronic wounds

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	which are at risk of infection or show signs of infection.
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:	EN ISO 13485: 2016 EN ISO 14971: 2019 EN ISO 15223-1: 2021 EN ISO 11737-1:2018 EN ISO 11135:2014+A1:2019
References to any CS:	N/A
Identification of Notified Body:	BSI Group The Netherlands B.V. Notified Body Number 2797 Say Building John.M. Keynesplein 9 1066 EP Amsterdam Netherlands
Identification of the 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
	EC Technical Documentation Assessment Certificate No. CE MDR 739169, issued by BSI Notified Body Number 2797 in accordance with Annex IX chapter II of this Regulation
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<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: Mar 2, 2023 16:03:14 PM GMT</p> <p>Head of IC/ AWC Regulatory Affairs 93126E72C04E8A0495E4DBA7AE98</p> <p>Place of Issue: Deeside, Flintshire</p> <p>Date: Mar 2, 2023</p>

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Appendix A: List of Product Range Covered under this Declaration of Conformity


PR20-295

ICC	SAP	Description
420647	1703977	AQUACEL FOAM AG ADH HEEL(1X5)
420647	1703975	AQUACEL FOAM AG ADH HEEL(1X5) STER
420627	1703962	AQUACEL FOAMAGADH12.5X12.5(1X10)
420627	1703964	AQUACEL FOAMAGADH12.5X12.5(1X10)
420628	1703966	AQUACEL FOAMAGADH17.5X17.5(1X10)
420628	1703968	AQUACEL FOAMAGADH17.5X17.5(1X10)
420629	1703971	AQUACEL FOAM AG ADH 21X21(1X5)
420629	1703973	AQUACEL FOAM AG ADH 21X21(1X5)
420648	1703979	AQUACEL FOAM AG ADH SACRAL(1X5)
420648	1703981	AQUACEL FOAM AG ADH SACRAL(1X5)
420649	1703961	AQUACEL FOAM AGADH12.5X12.5(1X3)
420681	1705404	AQUACEL FOAM AG ADH 10X10CM 1x10PK
420681	1705405	AQUACEL FOAM AG ADH 10X10CM 1x10PK
420805	1707750	AQUACEL FOAM AG ADH 8X8CM (1X10)
420805	1707749	AQUACEL FOAM AG ADH 8X8CM (1X10) STER
420807	1707758	AQUACEL FOAM AG ADH 25X30CM (1X5) STER
420807	1707759	AQUACEL FOAM AG ADH 25X30CM 1X5
421491	1713242	AQUACEL FOAM AG SACRAL (1X3)

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PR20-298

ICC	SAP	Description
420639	1704010	AQUACEL FOAM AG N/ADH 5X5(1X10)
420639	1704008	AQUACEL FOAM AG N/ADH 5X5(1X10)
420642	1704014	AQUACEL FOAM AG N/ADH10X10(1X10)
420642	1704016	AQUACEL FOAM AG N/ADH10X10(1X10)
420644	1704019	AQUACEL FOAM AG N/ADH 15X15(1X3)
420645	1704020	AQUACEL FOAM AG N/ADH 15X15(1X5)
420645	1704022	AQUACEL FOAM AG N/ADH 15X15(1X5)
420646	1704026	AQUACEL FOAM AG N/ADH 20X20(1X5)
420646	1704024	AQUACEL FOAM AG N/ADH 20X20(1X5)
420806	1707754	AQUACEL FOAM AG NADH 15X20CM (1X5)
420806	1707755	AQUACEL FOAM AG NADH 15X20CM (1X5)

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Revision History

Rev No	Date	Comment	Author
1	30/01/2023	Initial issue of Declaration of conformity under EU Medical Device Regulation (EU) 2017/745	Ramona Eichhorn
2	Mar 2, 2023	Technical documentation updated to demonstrate compliance to The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended).	Ramona Eichhorn