	Approved Date:	12-Oct-2021		
	Status:	Approved	Version:	1.0, CURRENT
	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

Technical Documentation MDR OSTTF 14 – Adhesive Barrier Spray


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

We hereby declare that the 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:	Refer to Appendix A
GMDN Code and Term Name:	Refer to Appendix A
EMDN Code and Term Description:	Refer to Appendix A
CND Code and Title:	Refer to Appendix A
Basic UDI-DI:	Refer to Appendix A
Identification of the device(s) concerned:	Refer to Appendix A
Catalogue Number:	Refer to Appendix A
Intended Purpose:	Protection of skin from the damaging effects of bodily waste, enzymes, and adhesives.
Risk Classification:	Class I as per Rule 1 in Annex VIII
Conformity Assessment Route:	Annex II and III of EU Medical Device Regulation (EU) 2017/745
Relevant Harmonised Standards:	None


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References to any CS:	None
Identification of Notified Body:	Not Applicable - Class I non-sterile device
Identification of the Certificate(s):	Quality Management System Certificate No. MD 670405, issued by BSI
	EC Technical Documentation Assessment Certificate No. Not applicable – Class I non-sterile devices.
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p>Name:</p> <p>Gary Barrett</p>  <p>Signature: _____</p> <p>Vice President, Regulatory Affairs</p> <p>Place of Issue: Deeside, Flintshire</p> <p>Date: Nov 4, 2021</p>

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

ICC Code	SAP Code	REF code (If applicable)	Product Description	GMDN Code and Term Name	EMDN Code and Term Description	CND Code and Title	Basic UDI-DI	Specification Number
420790	1706528	TR 104	ConvaTec Silesse™ Sting Free Skin Barrier, 50 ml Spray	58978 - Synthetic-polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0026FD	TF21-030
413502	1708249	N/A	Sensi-Care™ Sting Free Barrier Spray	58978 - Synthetic-polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0026FD	TF21-030
420797	1706535	N/A	SENSI-CARE SPRAY BARRIER TR109 (1PK x 28ML)	58978 - Synthetic-polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0027FF	TF21-032
420797	1708480	TR 109	CONVATEC SILESSE STING FREE BARRIER SPRAY (1 PK x 28 ML)	58978 - Synthetic-polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0027FF	TF21-032

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Revision History

<i>Rev no</i>	<i>Date</i>	<i>Comment</i>
1.0	26/May/2021	Initial Release of the Declaration of Conformity under the Medical Device Regulation (EU) 2017/745
2.0	1/Nov/2021	Updated to current template.