

	Approved Date:	12-Oct-2021		
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	Artifact Name:	Form	Name:	FORM-014357
	Title:	WI-0506 Declaration of Conformity Form		

EU Declaration of Conformity

Technical Documentation MDR OSTTF 13 – Adhesive Barrier Wipes

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 devices.
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
037444EU	1094026	N/A	ConvaCare Protective Barrier Wipe 100's	58978 - Synthetic -polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0036FG	TF21-025
037444WE	1020972	N/A	ConvaCare Protective Barrier Wipe 100's	58978 - Synthetic -polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0036FG	TF21-025
037444CE	1094025	N/A	ConvaCare Protective Barrier Wipe 100's	58978 - Synthetic -polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0036FG	TF21-025
420789	1706527	TR103	ConvaTec Silesse Sting Free Skin Barrier Wipes, 30 Ct.	58978 - Synthetic -polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0025FB	TF21-029
413501	1708248	N/A	Sensi-Care Sting Free Skin Barrier Wipe	58978 - Synthetic -polymer liquid barrier dressing, non-sterile	A108004 – Protective films/sprays for peristomal skin	A108004 – Protective film/spray for peristomal skin	768455OST0025FB	TF21-029

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Revision History

Rev no	Date	Comment
1.0	26/May/2021	Initial Release.
2.0	14/Oct/2021	Updated to current template and added SAP 1706527 and 1708248 per TF21-029.