

	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 011 – Adhesive remover wipes

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:	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:	Aids in the removal of all adhesives including skin barriers, flanges, tapes, and hydrocolloid dressings.
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
References to any CS:	None

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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><b>Name:</b> Gary Barrett</p> <p><b>Signature:</b> </p> <p>Signature: Gary Barrett          Signing Reason: I approve this document          Signing Time: Nov 4, 2021   8:43:05 PM GMT          A40D1F939D7141E182BD080455A1B09E</p> <p>Vice President, Regulatory Affairs          Place of Issue: Deeside, Flintshire, United Kingdom</p> <p>Date: Nov 4, 2021</p>

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



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ICC code	SAP code	Product name	PR/DS #	GMDN code and term	Basic UDI-DI	CND nomenclature / EMDN code and term
037443	1094208	CONVACARE ADH REMOVER WIPE (1X100PK) EUR	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
037443	1095053	CONVACARE ADH REMOVER WIPE (1X100PK) IT	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
037443	1094207	CONVACARE ADH REMOVER WIPE (1X100PK) WEU	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
037443	1020971	CONVACARE ADH REMOVER WIPE (1X100PK) SCN	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
037443	1094206	CONVACARE ADH REMOVER WIPE (1X100PK) CEU	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
037443	1003511	CONVACARE ADH REMOVER WIPE (1X100PK) INT	TP12-024	60494-Patient medical adhesive remover	768455OST0035FE	A108005-Adhesive removers
420788	1706526	NILTAC ADHESIVE REMOVER WIPE TR102 (1X30 PACK)	TP21-028	60494-Patient medical adhesive remover	768455OST0028FH	A108005-Adhesive removers
413500	1708247	SENSI-CARE ADH REMOVER WIPE (1X30PK)	TP21-028	60494-Patient medical adhesive remover	768455OST0028FH	A108005-Adhesive removers

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### Revision History

<i>Rev no</i>	<i>Date</i>	<i>Comment</i>	<i>Author</i>
1.0	02/11/2021	Initial Release. This DoC combines all DoCs associated with Revision 1 of OSTTF-011. This DoC includes all ICCs/SAPs supported by OSTTF-011	Mena Botrous