	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 010


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:	Refer to Appendix A
Risk Classification:	Class I; Refer to the rule in Appendix A for the specific rule of 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: Gary Barrett</p> <p>Signature: </p> <p>Signer Name: Gary Barrett Signing Reason: I approve this document Signing Time: Nov 4, 2021 8:43:32 PM GMT A40D1F939D7141E182BD08045A1B09E</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	Basic UDI-DI	PR/DS #	DHF #	GMDN code	GMDN term	CND nomenclature/EMDN code and term	Rule #	Intended purpose
022736	1003019	VISI-FLOW™ STOMA CONE 1X1PK IT	768455OST0007F9	PR10-028	30	58888	Colostomy irrigation kit, reusable	A108007 – Irrigation cone	5	Colostomy patients who wish to use irrigation procedures
401989	1158057	VISI-FLOW™ IRRIGATOR W/CONE (1X1PK) FR	768455OST0007F9	PR10-126	30	58888	Colostomy irrigation kit, reusable	A100399 – Ostomy irrigation systems - others	5	Colostomy patients who wish to use irrigation procedures
650610	1100587	VISI-FLOW™ IRRIGATOR NATURA (1PK)DE/NL	768455OST0007F9	PR10-126	30	58888	Colostomy irrigation kit, reusable	A100399 – Ostomy irrigation systems - others	5	Colostomy patients who wish to use irrigation procedures
022800	1003093	VISI-FLOW™ IRRIGATOR KIT45MM MOD 1X1PK IT	768455OST0007F9	PR10-160	30	58888	Colostomy irrigation kit, reusable	A100301 – Ostomy irrigation kits	5	Colostomy patients who wish to use irrigation procedures
175671	1021722	STOMADRESS SLEEVE IRRIG 50MM (1X30PK) DE	768455OST0006F7	DS10-035	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
175619	1176615	IRIDRESS SLEEVE IRRIG 1PC 50MM (1X30PK) FR	768455OST0006F7	DS10-035	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
175612	1024691	IRIDRESS SLEEVE IRRIG 1PC 50MM(1X10PK)IT	768455OST0006F7	DS10-035	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
175612	1024692	IRIDRESS SLEEVE IRRIG 1PC 50MM(1X10PK)NL	768455OST0006F7	DS10-035	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
175612	1024693	IRIDRESS SLEEVE IRRIG 1PC 50MM(1X10PK)SE	768455OST0006F7	DS10-035	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
125010	1021047	C/HESIVE 2S SLEEVE IRRIG 38MM(1X10PK)EEU	768455OST0006F7	DS10-090	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
125011	1021052	C/HESIVE 2S SLEEVE IRRIG 45MM (1X10PK)BE	768455OST0006F7	DS10-090	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
125011	1021053	C/HESIVE 2S SLEEVE IRRIG 45MM(1X10PK)EEU	768455OST0006F7	DS10-090	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma

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ICC code	SAP code	Product name	Basic UDI-DI	PR/DS #	DHF #	GMDN code	GMDN term	CND nomenclature/EMDN code and term	Rule #	Intended purpose
125011	1021056	C/HESIVE+ 2 SLEEVE IRRIG 45MM (1X10PK)SE	768455OST0006F7	DS10-090	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma
125012	1021061	C/HESIVE+ 2 SLEEVE IRRIG 57MM (1X10PK)SE	768455OST0006F7	DS10-090	176	58889	Colostomy irrigation sleeve	A100302 – Ostomy waste/irrigation, bags	1	Collection of stomal output following irrigation of the stoma

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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-010. This DoC includes all ICCs/SAPs supported by OSTTF-010.	Mena Botrous