

EU Declaration of Conformity
Adhesive Supplements Non Sterile
Technical Documentation MDR OSTTF 002

Issued by: ConvaTec

We hereby declare;

- that the listed product/s comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745 and any other applicable European Union legislation
- that this EU declaration of conformity is issued under the sole responsibility of ConvaTec.

Legal Manufacturer:	ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU, United Kingdom
Single Reg # (SRN):	GB-MF-000001770
Authorized Representative:	Unomedical a/s, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark
Product Name:	Refer to Appendix A
Basic UDI-DI:	Refer to Appendix A
Intended Use:	Refer to Appendix A
GMDN Code & Name:	Refer to Appendix A
EMDN Code & Description:	Refer to Appendix A
Device(s) & Catalogue Number:	Refer to Appendix A
Risk Class:	Class I (MDR Annex VIII)
Notified Body:	Self Certified
Certificate(s):	N/A

**Legal Manufacturer
authorized signature:**

Signature:

Signed by:
Courtney Smith

Signer Name: Courtney Smith
Signing Reason: I approve this document
Signing Time: Sep 23, 2024 | 8:53:09 PM BST

Date: Sep 23, 2024

18C584297FF34C80A5D3283D05D64343
Courtney Smith

Sr. Director, Regulatory Affairs Ostomy Care & Continence Care

Place of Issue: Boston, Massachusetts

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Appendix A: Products


Product Name	Stomahesive & Varihhesive Wafer	
Basic UDI	768455OST0012F2	
Intended Use	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	
GMDN Code & Name	46207 – Peristomal/peri wound dressing	
EMDN Code & Description	A108001 – Rings / Bezels / Plates for peristomal skin	
ICC Codes	SAP Code	Product Description
021713	1002897	STOMAHESIVE WFR 10X10CM (1X5PK) FR
021713	1002898	STOMAHESIVE WFR 10X10CM (1X5PK) DE
021713	1002899	STOMAHESIVE WFR 10X10CM (1X5PK) SCN
021713	1002900	STOMAHESIVE WFR 10X10CM (1X5PK) NL
021713	1002901	STOMAHESIVE WFR 10X10CM (1X5PK) IT
021713	1002902	STOMAHESIVE WFR 10X10CM (1X5PK) GB
021737	1002909	STOMAHESIVE WFR 20X20CM(1X3PK) NL
021737	1002910	STOMAHESIVE WFR 20X20CM (1X3PK) GB
021737	1012456	STOMAHESIVE WFR 20X20CM (1X3PK) DE
021740	1178343	STOMAHESIVE WFR 20X20CM (1X5PK) FR
168515	1024586	VARIHESIVE WFR 10X10CM (1X5PK) NL

Product Name	Orabase, Orahesive & Stomahesive Powder	
Basic UDI	768455OST0013F4	
Intended Use	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	
GMDN Code & Name	46207 - Peristomal/peri wound dressing	
EMDN Code & Description	A108003 Protective powder for peristomal skin	
ICC Codes	SAP Code	Product Description
025535	1022273	ORAHESIVE POWDER 25G (1X1PK) GB
025535	1022274	STOMAHESIVE POWDER 25G (1X1PK) DE/EEU
025535	1022275	ORABASE POWDER 25G (1X1PK) IT
025535	1022276	ORAHESIVE 25G (1X1PK) NL
025535	1022277	STOMAHESIVE POWDER (1X1PK) SE
025535	1103401	STOMAHESIVE POWDER (1BTLX25G) ES
025535	1192418	ORAHESIVE POWDER 25G (1X1PK) CEE

Product Name	Orabase & Stomahesive Paste	
Basic UDI	768455OST0014F6	
Intended Use	Orabase Paste is intended to absorb moisture and protect skin from damage. Stomahesive® Paste is intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as a filler for skin folds and uneven skin surfaces.	
GMDN Code & Name	46207 - Peristomal/peri wound dressing	
EMDN Code & Description	A108001 Rings / Bezels / Plates for peristomal skin	
ICC Codes	SAP Code	Product Description
129730	1024573	ORABASE PASTE (1TUBEX30G) GB
129730	1192419	STOMAHESIVE ORABASE PASTE (1X1PK)CEE
183910	1000745	STOMAHESIVE PASTE (1TUBEX60G) FR
183910	1000746	STOMAHESIVE PASTE (1TUBEX60G) DE
183910	1000747	STOMAHESIVE PASTE (1TUBEX60G) SCN
183910	1000749	STOMAHESIVE PASTE (1TUBEX60G) BE
183910	1000750	STOMAHESIVE PASTE (1TUBEX60G) IT
183910	1000751	STOMAHESIVE PASTE (1TUBEX60G) ES
183910	1000753	STOMAHESIVE PASTE (1TUBEX60G) GB
183910	1052383	STOMAHESIVE PASTE (1TUBEX60G) CEU
183910	1231164	STOMAHESIVE PASTE (1TUBEX56.7G) INT

Product Name	Stomahesive Seals	
Basic UDI	768455OST0012F2	
Intended Use	Adhesive Patches and Seals are intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	
GMDN Code & Name	46207 - Peristomal/peri wound dressing	
EMDN Code & Description	A108001 Rings / Bezels / Plates for peristomal skin	
ICC Codes	SAP Code	Product Description
413503	1708087	STOMAHESIVE SEAL 48MM (1X10PK) INT
413504	1708089	STOMAHESIVE SEAL THIN 48MM (1X10PK) INT
413505	1708090	STOMAHESIVE OSTOMY SEAL 98MM (1X10) INT

Product Name	Esenta Strips	
Basic UDI	768455OST0041F9	
Intended Use	Strips are intended to be used as additional fixation for the edges of skin barriers around the stoma.	
GMDN Code & Name	16866 - Dressing-fixation skin adhesive tape, non-silicone	
EMDN Code & Description	A108008 - Adhesives for Abdominal Ostomy Devices	
ICC Codes	SAP Code	Product Description
423824	1738600	ESENTA THIN STRIPS 3X11CM (1X60PK) EUR
423825	1738601	ESENTA THIN CURVE 3X9CM (1X60PK) EUR
423826	1738602	ESENTA THIN CURVE 3X9CM (1X80PK) NAI
423827	1738603	ESENTA THIN XL SEMI CIRCLE (1x20PK) EUR
423941	1747408	ESENTA THIN STRIPS 5X11CM (1X30PK)EUR
423943	1747410	ESENTA THIN STRIPS 5X11CM (1X20PK)EUR
423944	1747411	ESENTA THIN STRIPS 3X11CM (1X15PK)EUR
423945	1747424	ESENTA THIN CURVE 3X9CM (1X20PK) EUR
423942	1747409	ESENTA THIN STRIPS 5X22CM (1X20PK)EUR
423942	1747409	ESENTA THIN STRIPS 5X22CM (1X20PK)EUR

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	Title:	Declaration of Conformity Form		

Revision History

Revision	Reason for revision	Date
01	Initial Release. This DoC combines all DoCs associated with Revision 1 of OSTTF-002. This DoC includes all ICCs/SAPs supported by OSTTF-002.	02 Sept 2021
02	Addition of Esenta thin Strips as they have been adopted into OSTTF-002.	19 July 2023
03	Addition of 3 further codes for Esenta Strips, Transfer to new Template, removal of discontinued codes.	13 Sept 2024
04	Addition of a new code for Esenta Strips, ESENTA THIN strips 5X22CM (1X20PK)EUR, SAP: 1747409, ICC: 423942	As per sign off date

Trade/Brand Names for the Czech Republic

423941 Vyrovnávací pásy Esenta, rovný tvar

423942 Vyrovnávací pásy Esenta, rovný tvar