

**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.

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

**Legal Manufacturer authorized signature:**

Signed by:  
*Courtney Smith*

 Signer Name: Courtney Smith  
Signing Reason: I approve this document  
Signing Time: May 23, 2025 | 6:13:35 PM BST

**Signature:** 18C584297FF34C80A5D3283D05D64343 **Date:** May 23, 2025  
Courtney Smith

Sr. Director, Regulatory Affairs Ostomy Care & Continence Care  
Place of Issue: Boston, Massachusetts

**Appendix A: Products**

<b>Product Name</b>	Stomahesive & Varihhesive Wafer	
<b>Basic UDI</b>	768455OST0012F2	
<b>Intended Use</b>	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	
<b>GMDN Code &amp; Name</b>	46207 – Peristomal/peri wound dressing	
<b>EMDN Code &amp; Description</b>	A108001 – Rings / Bezels / Plates for peristomal skin	
<b>ICC Codes</b>	<b>SAP Code</b>	<b>Product Description</b>
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

<b>Product Name</b>	Orabase, Orahesive & Stomahesive Powder	
<b>Basic UDI</b>	768455OST0013F4	
<b>Intended Use</b>	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	
<b>GMDN Code &amp; Name</b>	46207 - Peristomal/peri wound dressing	
<b>EMDN Code &amp; Description</b>	A108003 Protective powder for peristomal skin	
<b>ICC Codes</b>	<b>SAP Code</b>	<b>Product Description</b>
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

<b>Product Name</b>	Orabase & Stomahesive Paste	
<b>Basic UDI</b>	768455OST0014F6	
<b>Intended Use</b>	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.	
<b>GMDN Code &amp; Name</b>	46207 - Peristomal/peri wound dressing	
<b>EMDN Code &amp; Description</b>	A108001 Rings / Bezels / Plates for peristomal skin	
<b>ICC Codes</b>	<b>SAP Code</b>	<b>Product Description</b>
129730	1024573	ORABASE PASTE (1TUBEX30G) GB
129730	1192419	STOMAHESIVE ORABASE PASTE (1X1PK)CEE
183910	1040001	ESENTA STOMAHESIVE PASTE (1TUBEX60G) FR
183910	1739999	ESENTA STOMAHESIVE PASTE (1TUBEX60G) DE
183910	1729233	ESENTA STOMAHESIVE PASTE (1TUBEX60G) SCN
183910	1739997	ESENTA STOMAHESIVE PASTE (1TUBEX60G) BE
183910	1740003	ESENTA STOMAHESIVE PASTE (1TUBEX60G) IT
183910	1740000	ESENTA STOMAHESIVE PASTE (1TUBEX60G) ES
183910	1740002	ESENTA STOMAHESIVE PASTE (1TUBEX60G) GB
183910	1739998	ESENTA STOMAHESIVE PASTE (1TUBEX60G) CEU
183910	1729233	ESENTA S/HESIVE PASTE 1TUBEX60G SCN

<b>Product Name</b>	Stomahesive Seals	
<b>Basic UDI</b>	768455OST0012F2	
<b>Intended Use</b>	Adhesive Patches and Seals are intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	
<b>GMDN Code &amp; Name</b>	46207 - Peristomal/peri wound dressing	
<b>EMDN Code &amp; Description</b>	A108001 Rings / Bezels / Plates for peristomal skin	
<b>ICC Codes</b>	<b>SAP Code</b>	<b>Product Description</b>
413503	1740004	ESENTA STOMAHESIVE SEAL 48MM (1X10PK) INT
413504	1729239	ESENTA STOMAHESIVE SEAL THIN 48MM (1X10PK) INT
413505	1740005	ESENTA STOMAHESIVE OSTOMY SEAL 98MM (1X10) INT

<b>Product Name</b>	Esenta Strips	
<b>Basic UDI</b>	768455OST0041F9	
<b>Intended Use</b>	Strips are intended to be used as additional fixation for the edges of skin barriers around the stoma.	
<b>GMDN Code &amp; Name</b>	16866 - Dressing-fixation skin adhesive tape, non-silicone	
<b>EMDN Code &amp; Description</b>	A108008 - Adhesives for Abdominal Ostomy Devices	
<b>ICC Codes</b>	<b>SAP Code</b>	<b>Product Description</b>
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

 <b>convatec</b> – forever caring –	Effective Date:	15-May-2024		
	Status:	Effective	Version:	4.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	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
05	<p><b>Revision 1</b> CCR 1596334 ESENTA rebranding project to rebrand Stomahesive Pastes &amp; Stomahesive Seals to reflect New rebrand name ESENTA. Esenta Stomahesive Pastes, ESENTA Stomahesive Seals and ESENTA. NEW SAP#'s, NEW UDI#'s assigned.</p> <p><b>Revision 2</b> Mode of action for Stomahesive Pastes change from type B to type A change since the material changed (Tube, Cap and Primary Packaging),</p> <p><b>Revision 3</b> the following statement was removed from the the intended use statement regarding the use of Stomahesive Pastes on the labels of some tubes, cartons and IFUs that included the following statement "The paste can also be used to protect exposed skin around fistula sites, to fill irregularities and depressions on peristomal skin around colostomies, ileostomies and urostomies, and act as a filler for skin folds, uneven skin surfaces, and scars." because the use of fistulas was not mentioned in design and development documentation and is not in the intended use statement. DS10-112 and DL10-112 were updated and put into Appendix E</p> <p>Added US SAP# 1739996 because it is sold in the UK. To show product conforms to regulations to the UKCA symbol that was put on the labelling.</p> <p><b>Revision 3.1</b> Removed SAP 1729236 Stomahesive Paste SKU not sold in the EU or UK, SAP 1739996 Paste laminates need to have UKCA removed (Artcode 1740013A1), SAP 147002 Paste laminates Arcode 1740011A1 add UKCA and Seals – to align UKCA symbols on all layers of packaging (Artcodes1740007 and 1740008)</p> <p>Updated product descriptions on Pastes, Seals and Wafers.</p> <p><b>Stomahesive &amp; Verihesive Wafer</b> added to DHF 1071 in above cover sheet.</p>	23 May 2025

	Deleted SAP 1231164 Paste Esenta S/Hesive INT not sold in the EU.	
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## **Trade/Brand Names for the Czech Republic**

413503 Esenta těsnicí kroužky Stomahesive

413504 Esenta těsnicí kroužky Stomahesive

413505 Esenta těsnicí kroužky Stomahesive

183910 Esenta pasta Stomahesive