

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 |
| Actor ID/SRN | DK-AR-000000941 |
| 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 |
| | Date: |

**Legal Manufacturer
authorized signature:**

Signed by:

 Signer Name: Courtney Smith
 Signing Reason: I approve this document
 Signing Time: Sep 18, 2025 | 5:42:45 PM BST
 18C584297FF34C80A5D3283D05D64343

Sep 18, 2025

Signature:

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 & Varihesive 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 | 1739977 | ESENTA S/HESIVE PDR 25G (1X1PK) GB This code previously SAP 1022273 ORAHESIVE POWDER 25G (1X1PK) GB was combined with 1739977 GB/FR/NL/TR |
| 025535 | 1022273 | ORAHESIVE POWDER 25G (1X1PK) GB |
| 025535 | 1739980 | ESENTA S/HESIVE PDR 25G DE/IT |
| 025535 | 1022274 | STOMAHESIVE POWDER 25G (1X1PK) DE/EEU |
| 025535 | 1022275 | ORABASE POWDER 25G (1X1PK) IT |
| 025535 | 1192418 | ORAHESIVE POWDER 25G (1X1PK) CEE |
| 025535 | 1022276 | ORAHESIVE 25G (1X1PK) NL |
| 025535 | 1022277 | STOMAHESIVE POWDER (1X1PK) SE |
| 025535 | 1739994 | ESENTA S/HESIVE PDR 25G SCN |
| 025535 | 1739984 | ESENTA S/HESIVE PDR 25G ES |
| 025535 | 1103401 | STOMAHESIVE POWDER (1BTLX25G) ES |
| 025535 | 1739974 | ESENTA S/HESIVE PDR 25G CEE |


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|------------------------------------|--|---|
| 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 | 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 |
| 183910 | 1000742 | STOMAHESIVE PASTE (1TUBEX56.7G) US |
| 183910 | 1000749 | STOMAHESIVE PASTE (1TUBEX60G) BE |
| 183910 | 1052383 | STOMAHESIVE PASTE (1TUBEX60G) CEU |
| 183910 | 1000746 | STOMAHESIVE PASTE (1TUBEX60G) DE |
| 183910 | 1000751 | STOMAHESIVE PASTE (1TUBEX60G) ES |
| 183910 | 1000745 | STOMAHESIVE PASTE (1TUBEX60G) FR |
| 183910 | 1000753 | STOMAHESIVE PASTE (1TUBEX60G) GB |
| 183910 | 1000750 | STOMAHESIVE PASTE (1TUBEX60G) IT |
| 183910 | 1000747 | STOMAHESIVE PASTE (1TUBEX60G) SCN |
| 183910 | 1739996 | ESENTA STOMAHESIVE PASTE (1TUBEX56.7G) US |

| | | |
|------------------------------------|---|--|
| 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 | 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 |
| 413503 | 1708087 | STOMAHESIVE SEAL 48MM (1X10PK) INT |
| 413504 | 1708089 | STOMAHESIVE SEAL THIN 48MM (1X10PK) INT |
| 413505 | 1708090 | STOMAHESIVE OSTOMY SEAL 98MM (1X10) INT |

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| 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 | |

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| 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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|--|-----------------|--------------------------------|----------|----------------|
|  | 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>Revision 1 CCR 1596334 ESENTA rebranding project to rebrand Stomahesive Pastes & 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>Revision 2 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>Revision 3 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>Revision 3.1 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>Stomahesive & Verihesive Wafer added to DHF 1071 in above cover sheet.</p> | 23 May 2025 |

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|---|---|-------------|
| | Deleted SAP 1231164 Paste Esenta S/Hesive INT not sold in the EU. | 23 May 2025 |
| 6 | Added Actor ID/STRN DK-AR-000000941 | 28 MAY 2025 |
| 7 | Added /FR/NL/TR to the description for SAP 1022273 was combined with SAP 1739977, SAP code 1022277 updated to new SAP code 1739994 and SAP code 1103401 updated to new SAP code 1739984 | 29 Jul 2025 |
| 8 | Updated New SAP# from 1022274 to 1739980 and 1192418 to 1739974. Updated product description on 1739980 from DE/CEE to DE/IT | 12 Sep 2025 |
| 9 | Legacy codes affected by Esenta rebrand were erroneously omitted in previous version to reflect new SAP codes. Legacy codes are still in market cycling out therefore legacy codes for Esenta Pastes, Seals and Powders have been put back in this version. | 18-Sep-2025 |

Trade/Brand Names for the Czech Republic

25535 Pudr Esenta Stomahesive