

	Effective Date:	24-Jul-2020	CR:	CR-040524
	Status:	Effective	Version:	2.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	WI - Work Instruction	Name:	WI-0506
	Title:	Declaration of Conformity under EU Medical Device Regulation 2017/745		

## EU Declaration of Conformity

### Technical Documentation MDR OSTTF 002 – Adhesive Supplements

This Declaration of Conformity is issued under the sole responsibility of ConvaTec Limited.

We hereby declare that the 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 Product Description in list of products
GMDN Code and Title:	Refer to GMDN Code and Title in list of products
CND nomenclature:	Refer to CND Nomenclature in list of products
Basic UDI-DI:	Refer to Basic UDI-DI in list of products
Identification of the device(s) concerned:	Refer to Product Description in list of products
Catalogue Number:	Refer to ICC Code in list of products
Intended purpose:	Refer to intended purpose in list of products
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 Harmonized Standards:	N/A, at time of approval there are no Harmonized Standards to the Medical Device Regulation 2017/745
References to any CS:	Not Applicable
Identification of Notified Body:	Not Applicable - Class I non-sterile device

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Identification of the Certificate(s):	Quality Management System Certificate No. MD 670405, Issued by BSI
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>Vice President, Regulatory Affairs Place of Issue: Deeside, Flintshire, United Kingdom</p> <p><b>Date: September 2 2021</b></p>

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## List of Products

SAP Code	ICC Code	Product Description	Intended Purpose	GMDN Code and Title	Basic UDI-DI	CND Nomenclature	Specification Number
1002897	021713	STOMAHESIVE WFR 10X10CM (1X5PK) FR	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002898	021713	STOMAHESIVE WFR 10X10CM (1X5PK) DE	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002899	021713	STOMAHESIVE WFR 10X10CM (1X5PK) SCN	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002900	021713	STOMAHESIVE WFR 10X10CM (1X5PK) NL	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002901	021713	STOMAHESIVE WFR 10X10CM (1X5PK) IT	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002902	021713	STOMAHESIVE WFR 10X10CM (1X5PK) GB	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002909	021737	STOMAHESIVE WFR 20X20CM (1X3PK) NL	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1002910	021737	STOMAHESIVE WFR 20X20CM(1X3PK) GB	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1178343	021740	STOMAHESIVE WFR 20X20CM (1X5PK) FR	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073- Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	PR30-001
1022273	025535	ORAHESIVE POWDER UK (200X25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periwound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1022274	025535	ORABASE POWDER DE (200x25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periwound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1022275	025535	ORABASE POWDER IT (200X25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periwound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1022276	025535	ORAHESIVE POWDER NL (200x25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periwound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040



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1022277	025535	ORAHESIVE POWDER SCN (200x25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1192418	025535	STOMAHESIVE POWDER CEE (200x25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1103401	025535	STOMAHESIVE POWDER PROTECTOR ES (200x25g)	Intended to absorb moisture and protect skin from damage, and to facilitate the application of ostomy systems.	46207 - Peristomal/ Periound Dressing	768455OST0013F4	A108003 - Protective powder for peristomal skin	TP13-040
1024573	129730	ORABASE PASTE 30G (1X1PK) UK	Orabase Paste is intended to absorb moisture and protect skin from damage	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	TP13-039
1024574	129730	ORABASE PASTE 30G (1X1PK) DE	Orabase Paste is intended to absorb moisture and protect skin from damage	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	TP13-039
1192419	129730	ORABASE PASTE 30G (1X1PK) CEE	Orabase Paste is intended to absorb moisture and protect skin from damage	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	TP13-039
1024578	129750	ORABASE PASTE 100G (1X1PK) SCN	Orabase Paste is intended to absorb moisture and protect skin from damage	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	TP13-039
1024586	168515	VARIHESIVE WFR 10X10CM (1X5PK)	Intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073 - Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	DS20-014
1000750	183910	STOMAHESIVE PASTE (1TUBEX60G) IT	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1000745	183910	STOMAHESIVE PASTE (1TUBEX60G) FR	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1000751	183910	STOMAHESIVE PASTE (1TUBEX60G) ES	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1000746	183910	STOMAHESIVE PASTE (1TUBEX60G) DE	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1000749	183910	STOMAHESIVE PASTE (1TUBEX60G) BE	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1231164	183910	STOMAHESIVE PASTE (1TUBEX56.7G) INT	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001

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1000747	183910	STOMAHESIVE PASTE (1TUBEX60G) SCN	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periwound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1052383	183910	STOMAHESIVE PASTE (1TUBEX60G) CEU	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periwound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1000753	183910	STOMAHESIVE PASTE (1TUBEX60G) GB	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.	46207 - Peristomal/Periwound Dressing	768455OST0014F6	A108001 - Protective paste/gel for peristomal skin	PR/DL10-001
1708087	413503	STOMAHESIVE SEAL 48MM (1X10PK)	Adhesive Patches and Seals are intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073-Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	DS10-112
1708089	413504	STOMAHESIVE SEAL THIN 48MM (1X10PK)	Adhesive Patches and Seals are intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073-Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	DS10-112
1708090	413505	STOMAHESIVE SEAL 98MM (1X10PK) INT	Adhesive Patches and Seals are intended to provide protection for peristomal skin by filling skin irregularities and depressions to improve adhesion of ostomy systems.	31073-Intestinal stoma shield/support belt, single-use	768455OST0012F2	A100201- Ostomy plates	DS10-112

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## Revision History

<i>Rev no</i>	<i>Date</i>	<i>Comment</i>	<i>Author</i>
1.0	02/Sep/2021	Initial Release. This DoC combines all DoCs associated with Revision 1 of OSTTF-002. This DoC includes all ICCs/SAPs supported by OSTTF-002.	L. Bleyendaal