

EU Declaration of Conformity
Pouch System Supplements – Non-sterile
Technical Documentation MDR OSTTF 003

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:	Pouch System Supplements
Intended Use/ Intended Purpose:	Clips and Closures – Clips/closures are intended for closing drainable ostomy pouches. Stoma Caps – Stoma Caps are intended to be used to manage of stomal output for short periods of time or following irrigation. Conve Inserts – To add convexity to two-piece systems. Low Pressure Adaptors – Used to reduce pressure on the abdomen during pouch coupling, particularly right after surgery. Security Belt – System 2 Security Belts are intended to provide extra security for ostomy systems by securing the ostomy pouch around the user's waist. Diamonds – Esenta™ Diamonds™ are intended to gel the contents of an ileostomy or colostomy pouch, or a faecal management system collection bag, and to reduce or eliminate unwanted odours and excess flatus.
Basic UDI-DI:	See Appendix A
GMDN Code & Term Name:	See Appendix A
EMDN Code & Description:	A108006 Supporting Belt A100205 Two-Pieces Ostomy Devices, Caps A108099 Ostomy Accessories Devices-Other A100201 Ostomy Plates A100299 Ostomy Devices, Two-Pieces - Others
Device(s) & Cat. #:	Refer to Appendix A

Risk Classification:	Class I as per Rule 1 of Annex VIII
Notified Body:	Not applicable, Class I non-sterile device
Certificate(s):	Not applicable - -Class I non-sterile device
Legal Manufacturer authorized signature:	Signature: _____ Date: See signature Courtney Smith Sr. Director, Regulatory Affairs Ostomy Care & Continence Care Place of Issue: Deeside, Flintshire Signed by: <i>Courtney Smith</i>  Signer Name: Courtney Smith Signing Reason: I approve this document Signing Time: Sep 18, 2024 3:24:06 PM BST 18C584297FF34C80A5D3283D05D64343

Appendix A: Products covered under this Declaration of Conformity

SAP	REF Code (ICC Code)	Description	Basic UDI-DI	GMDN Code
System 3 Plus Stoma Cap				
1021701	175611	IRIDRESS STOMACAP 1PC (1X30PK) FR	768455OST0021F3	31066
1024684	175611	COLODRESS+ STOMACAP (1X30PK) BE	768455OST0021F3	31066
1024685	175611	COLODRESS+ STOMACAP (1X30PK) GB	768455OST0021F3	31066
1024686	175611	STOMADRESS+ STOMACAP (1X30PK) DE	768455OST0021F3	31066
1024687	175611	STOMADRESS+ STOMACAP (1X30PK) IT	768455OST0021F3	31066
1024689	175611	STOMADRESS+ STOMACAP (1X30PK) SE	768455OST0021F3	31066
1189357	175611	STOMADRESS+ STOMACAP (1X30PK) EEU	768455OST0021F3	31066
System 92 Secure Plus				
1021065	125013	C/HESIVE 2 STOMACAP 38MM (1X25PK) SE	768455OST0021F3	31067
1021069	125014	C/HESIVE 2S FLANGE CAP 45MM (1X25PK) SE	768455OST0021F3	31067
1021073	125015	C/HESIVE 2S STOMA CAP 57MM (1X25PK) SE	768455OST0021F3	31067
System 2 Secure Plus Stoma Caps				
1097298	404108	NATURA STOMA CAP F+ TAN 45MM (1X25PK) DE	768455OST0021F3	31067
1097299	404109	NATURA STOMA CAP F+ TAN 57MM (1X25PK) DE	768455OST0021F3	31067
1097723	404108	NATURA STOMA CAP F+TAN 45MM(1X25PK) NL/GB	768455OST0021F3	31067
1097724	404109	NATURA STOMA CAP F+TAN 57MM(1X25PK) NL/GB	768455OST0021F3	31067
1097297	404107	NATURA STOMA CAP F+ TAN 38MM (1X25PK) DE	768455OST0021F3	31067
1097722	404107	NATURA STOMA CAP F+ TAN 38MM (1X25PK) NL/GB	768455OST0021F3	31067
1097298	404108	NATURA STOMA CAP F+ TAN 45MM (1X25PK) DE	768455OST0021F3	31067
Flexible Tail Closure				
1000600	175633	FLEX TAIL CLSR (1X50PK) SCN	768455OST0016FA	37502
System 4/System 4 Secure Convex Insert				
1097541	404006	C/HESIVE NATURA CVX INS 19/38MM(1X5PK)DE	768455OST0018FE	47658
1097542	404007	C/HESIVE NATURA CVX INS 22/38MM(1X5PK)DE	768455OST0018FE	47658
1097543	404008	C/HESIVE NATURA CVX INS 25/38MM(1X5PK)DE	768455OST0018FE	47658
1097544	404009	C/HESIVE NATURA CVX INS 29/45MM(1X5PK)DE	768455OST0018FE	47658
1097545	404010	C/HESIVE NATURA CVX INS 32/45MM(1X5PK)DE	768455OST0018FE	47658
1097546	404011	C/HESIVE NATURA CVX INS 35/45MM(1X5PK)DE	768455OST0018FE	47658
1097547	404012	C/HESIVE NATURA CVX INS 38/57MM(1X5PK)DE	768455OST0018FE	47658
1097550	404007	C/HESIVE NAT CVX INS 22/38MM(1X5PK)NL/GB	768455OST0018FE	47658
1097551	404008	C/HESIVE NAT CVX INS 25/38MM(1X5PK)NL/GB	768455OST0018FE	47658
1097552	404009	C/HESIVE NAT CVX INS 29/45MM(1X5PK)NL/GB	768455OST0018FE	47658
1097553	404010	C/HESIVE NAT CVX INS 32/45MM(1X5PK)NL/GB	768455OST0018FE	47658
1097554	404011	C/HESIVE NAT CVX INS 35/45MM(1X5PK)NL/GB	768455OST0018FE	47658
1097555	404012	C/HESIVE NAT CVX INS 38/57MM(1X5PK)NL/GB	768455OST0018FE	47658
1097556	404013	C/HESIVE NAT CVX INS 41/57MM(1X5PK)NL/GB	768455OST0018FE	47658
Curved Drainage Clip				
1021713	175652	CONVATEC TAIL CLIP CURVED (1X10PK) SE	768455OST0016FA	37502
Tail Clip				
175632	175632	CONVATEC CLIP DRN PCH (1X10PK) DE/NL/GB	768455OST0016FA	37502
Drainage Clip - Wire Style				
1024709	420832	CONVATEC SOFT WIRE TIES (1X50PK) GB	768455OST0016FA	37502
System 92 Secure Convex Insert				
1021247	125170	SURFIT+ CVX INS 19/38MM (1X5PK) INT	768455OST0018FE	47658
1021248	125170	C/HESIVE 2+ CVX INS 19/38MM (1X5PK) SE	768455OST0018FE	47658
1021252	125171	SURFIT+ CVX INS 22/38MM (1X5PK) INT	768455OST0018FE	47658
1021253	125171	C/HESIVE 2+ CVX INS 22/38MM (1X5PK) SE	768455OST0018FE	47658
1021257	125172	SURFIT+ CVX INS 25/38MM (1X5PK) INT	768455OST0018FE	47658

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SAP	REF Code (ICC Code)	Description	Basic UDI-DI	GMDN Code
1021258	125172	C/HESIVE 2+ CVX INS 25/38MM (1X5PK) SE	768455OST0018FE	47658
1021262	125173	SURFIT+ CVX INS 28/45MM (1X5PK) INT	768455OST0018FE	47658
1021263	125173	C/HESIVE 2+ CVX INS 28/45MM (1X5PK) SE	768455OST0018FE	47658
1021267	125174	SURFIT+ CVX INS 31/45MM (1X5PK) INT	768455OST0018FE	47658
1021268	125174	C/HESIVE 2+ CVX INS 31/45MM (1X5PK) SE	768455OST0018FE	47658
1021269	125175	C/HESIVE 2S CVX INS 35/45MM (1X5PK) BE	768455OST0018FE	47658
1021272	125175	SURFIT+ CVX INS 35/45MM (1X5PK) INT	768455OST0018FE	47658
1021273	125175	C/HESIVE 2+ CVX INS 35/45MM (1X5PK) SE	768455OST0018FE	47658
1021278	125176	C/HESIVE 2+ CVX INS 38/57MM (1X5PK) SE	768455OST0018FE	47658
1021282	125177	SURFIT+ CVX INS 41/57MM (1X5PK) INT	768455OST0018FE	47658
1021283	125177	C/HESIVE 2+ CVX INS 41/57MM (1X5PK) SE	768455OST0018FE	47658
System 2 Security Belt				
1021685	175507	C/HESIVE 2S BELT 42" (1X1PK) BE	768455OST0022F5	62951
1021686	175507	C/HESIVE 2+ BELT 42" (1X1PK) SE	768455OST0022F5	62951
1024619	175510	C/HESIVE SYS BELT (1X1PK) FR	768455OST0022F5	62951
1024620	175510	S/CARE S2 BELT (1X1PK) GB	768455OST0022F5	62951
1024621	175510	C/HESIVE SYS BELT (1X1PK) DE	768455OST0022F5	62951
1024622	175510	S/HESIVE SISTEMA 2 BELT (1X1PK) IT	768455OST0022F5	62951
1024624	175510	C/HESIVE SYS BELT (1X1PK) NL	768455OST0022F5	62951
1115621	175510	S2 BELT COLO/ILEO/URO (1X1PK) ES	768455OST0022F5	62951
1189356	175510	S/CARE S2 BELT (1X1PK) CEE	768455OST0022F5	62951
Sur-Fit Natura Low Pressure Adaptor				
1253614	401993	S-FIT NAT LOW PRESSURE ADPT45MM 1X10 EUR	768455OST0020EZ	56646
1253615	401994	S-FIT NAT LOW PRESSURE ADPT57MM 1X10 EUR	768455OST0020EZ	56646
1253639	401995	S-FIT NAT LOW PRESSURE ADPT70MM 1X10 EUR	768455OST0020EZ	56646
1253617	401996	S-FIT NAT LOW PRESSURE ADPT100MM1X10 EUR	768455OST0020EZ	56646
Diamonds™ gelling and odour control Sachets				
1739961	420791	ESENTA DIAMONDS ODOR CTRL 1X100 JAR	768455OST0019FG	58116
1739968	420792	ESENTA DIAMONDS ODOR CTRL 1X5PK	768455OST0019FG	58116
1739965	423831	ESENTA DIAMONDS ODOR CTRL (1X30) CTN	768455OST0019FG	58116

Trade/Brand Names for the Czech Republic

423831 Gelující sáčky Esenta Diamonds

420791 Gelující sáčky Esenta Diamonds