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EU Declaration of Conformity

Ostomy Appliance Belt DS40-001
System 3 Plus Stoma Cap DS10-069
System 92 Secure Plus Stoma Cap DS10-091
System 2 Secure Plus Stoma Caps DS10-159
Flexible Tail Closure DS40-004
System 4/System 4 Secure Convex Insert DS40-010
Tail Closure DS40-012
Curved Drainage Clip DS40-013
Tail Clip DS40-016
Drainage Clip - Wire Style DS40-017
System 92 Secure Convex Insert DS40-279
System 2 Security Belt DS40-280
Sur-Fit Natura Low Pressure Adaptor TP12-022
Diamonds™ gelling and odour control Sachets TP21-031
Technical Documentation MDR OSTTF 003


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

We hereby declare that the mentioned product/ 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:	Ostomy Belt Ostomy Appliance Belt Stomahesive Sistema 2 Cinture



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	<p>Combihesive Balta</p> <p>Varicare Belt</p> <p>Stomahesive WF</p> <p>Combihesive (with graphic of belt)</p> <p>Systeme Combihesive</p> <p>System 2 Belt</p> <p>Combihesive Belt</p> <p>Colodress Plus</p> <p>Stomadress Plus Stoma Cap</p> <p>System 92 Secure Plus Stoma Cap</p> <p>Flexi Tail Closure</p> <p>SURFIT®/SUR-FIT Plus®</p> <p>ConvaTec Straight Tail Closure</p> <p>Secure Tail Closure</p> <p>Curved Tail Clip</p> <p>Duolock</p> <p>Tail Clip</p> <p>Convatec Soft Wire Tie</p> <p>Natura® /Combihesive Natura®</p> <p>System 2 Security Belt</p> <p>Ostomy Appliance Belt</p> <p>Appliance Belt</p> <p>Ostomy Belt</p> <p>SUR-FIT Natura Low Pressure Adaptor</p> <p>Varicare Natura Low Pressure Adaptor</p> <p>ConvaTec Diamonds™ gelling and odour control Sachets</p>
GMDN Code and Term Name:	<p>62951 Ostomy appliance belt</p> <p>31066 One-piece intestinal ostomy bag, closed ended</p> <p>31067 Multiple-piece intestinal ostomy bag, closed-ended</p> <p>37502 Ostomy bag closure device</p> <p>47658 Ostomy convexity insert</p> <p>56646 Ostomy bag low pressure adaptor</p>

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	58116 Liquid excrement solidifier
EMDN Code and Term Description:	A108006 Supporting Belt A100205 Two-Pieces Ostomy Devices, Caps A108099 Ostomy Accessories Devices-Other A100201 Ostomy Plates A100299 Ostomy Devices, Two-Pieces - Others
Basic UDI-DI:	768455OST0022F5 – Ostomy Appliance Belt, System 2 Security Belt 768455OST0021F3– System 3 Plus Stoma Cap, System 92 Secure Plus Stoma Cap, System 2 Secure Plus Stoma Caps 768455OST0016FA and 768455OST0017FC – Flexible Tail Closure, Tail Closure, Curved Drainage Clip, Tail Clip, Drainage Clip - Wire Style 768455OST0018FE - System 4/System 4 Secure Convex Insert, System 92 Secure Convex Insert 768455OST0020EZ - Sur-Fit Natura Low Pressure Adaptor 768455OST0019FG - Diamonds™ gelling and odour control Sachets
Identification of the device(s) concerned:	Refer to Appendix A
Catalogue Number:	Refer to Appendix A
Intended Purpose:	System 2 Security Belts are intended to provide extra security for ostomy systems by securing the ostomy pouch around the user's waist. ConvaTec stoma caps are intended to be used to manage of stomal output for short periods of time or following irrigation. Flexible Tail closures are intended for closing drainable ostomy pouches System 4/System 4 Secure Convex Insert are intended to add convexity to two-piece systems. Tail Closures are intended for closing drainable ostomy pouches. Curved Tail Closures are intended for closing drainable ostomy pouches. Tail Clips are intended for closing drainable ostomy


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	<p>pouches.</p> <p>Soft Wire Tie are intended for closing drainable ostomy pouches.</p> <p>System 92 Secure Convex Insert are intended to add convexity to two-piece systems.</p> <p>System 2 Security Belts are intended to provide extra security for ostomy systems by securing the ostomy pouch around the user's waist.</p> <p>Low pressure adaptors are intended to be used to reduce pressure on the abdomen during pouch coupling, particularly right after surgery.</p> <p>ConvaTec Diamonds™ are intended to gel the semi-formed to liquid contents of an ileostomy or colostomy pouch, or a faecal management system collection bag, and to reduce or eliminate unwanted odours and excess flatus.</p>
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 Harmonised Standards:	<p>EN ISO 13485:2016</p> <p>EN ISO 14971:2019</p> <p>EN ISO 15223-1:2021</p>
References to any CS:	Not Applicable
Identification of Notified Body:	Not Applicable - Class I nonsterile device
Identification of the Certificate(s):	EC Quality Management System Certificate No. MD 670405, issued by BSI.
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p>Name: Courtney Smith</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>DocuSigned by:  Courtney Smith</p> <p> Signer Name: Courtney Smith Signing Reason: I approve this document Signing Time: Oct 20, 2023 4:58:39 PM BST 18C584297FF34C80A5D3283D05D64343</p> </div> <p>Signature: _____</p> <p>Sr. Director, Regulatory Affairs Ostomy Care & Continence Care</p> <p>Place of Issue: Deeside, Flintshire</p> <p>Date: 20 Oct 2023</p>

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Appendix A: List of Product Range Covered under this Declaration of Conformity

SAP Code	REF Code (ICC Code)	Product Description	Basic UDI-DI	GMDN Code
D40-001 Ostomy Appliance Belt				
1002813	175507	OSTOMY APPLIANCE BELT 42" (1X1PK) US & EU	768455OST0022F5	62951
DS10-069 System 3 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
DS10-091 System 92 Secure Plus Stoma Cap				
1021065	125013	C/HESIVE 2 STOMACAP 38MM (1X25PK) SE	768455OST0021F3	31067
1021069	125014	C/HESIVE 2 STOMACAP 45MM (1X25PK) SE	768455OST0021F3	31067
1021073	125015	C/HESIVE 2 STOMACAP 57MM (1X25PK) SE	768455OST0021F3	31067
DS10-159 System 2 Secure Plus Stoma Caps				
1097297	404107	NATURA STOMA CAP F+ TAN 38MM (1X25PK) DE	768455OST0021F3	31067


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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
1097723	404108	NATURA STOMA CAP F+ TAN 45MM (1X25PK) NL/GB	768455OST0021F3	31067
1097299	404109	NATURA STOMA CAP F+ TAN 57MM (1X25PK) DE	768455OST0021F3	31067
1097724	404109	NATURA STOMA CAP F+ TAN 57MM (1X25PK) NL/GB	768455OST0021F3	31067
DS40-004 Flexible Tail Closure				
1000600	175633	FLEX TAIL CLSR (1X50PK) SCN	768455OST0016FA	37502
DS40-010 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
1097550	404007	C/HESIVE NAT CVX INS 22/38MM(1X5PK)NL/GB	768455OST0018FE	47658
1097543	404008	C/HESIVE NATURA CVX INS 25/38MM(1X5PK)DE	768455OST0018FE	47658
1097551	404008	C/HESIVE NAT CVX INS 25/38MM(1X5PK)NL/GB	768455OST0018FE	47658
1097544	404009	C/HESIVE NATURA CVX INS 29/45MM(1X5PK)DE	768455OST0018FE	47658
1097552	404009	C/HESIVE NAT CVX INS 29/45MM(1X5PK)NL/GB	768455OST0018FE	47658
1097545	404010	C/HESIVE NATURA CVX INS 32/45MM(1X5PK)DE	768455OST0018FE	47658
1097553	404010	C/HESIVE NAT CVX INS 32/45MM(1X5PK)NL/GB	768455OST0018FE	47658
1097546	404011	C/HESIVE NATURA CVX INS 35/45MM(1X5PK)DE	768455OST0018FE	47658
1097554	404011	C/HESIVE NAT CVX INS 35/45MM(1X5PK)NL/GB	768455OST0018FE	47658




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1097547	404012	C/HESIVE NATURA CVX INS 38/57MM(1X5PK)DE	768455OST0018FE	47658
1097555	404012	C/HESIVE NAT CVX INS 38/57MM(1X5PK)NL/GB	768455OST0018FE	47658
1097548	404013	C/HESIVE NATURA CVX INS 41/57MM(1X5PK)DE	768455OST0018FE	47658
1097556	404013	C/HESIVE NAT CVX INS 41/57MM(1X5PK)NL/GB	768455OST0018FE	47658
DS40-012 Tail Closure				
1000601	175635	SUR-FIT/ACTIVE LIFE TAIL CLSR (1X10PK) US (EU)	768455OST0016FA	37502
DS40-013 Curved Drainage Clip				
1021713	175652	CONVATEC TAIL CLIP CURVED (1X10PK) SE	768455OST0016FA	37502
DS40-016 Tail Clip				
1024707	175632	CONVATEC CLIP DRN PCH (1X10PK) DE/NL/GB	768455OST0016FA	37502
DS40-017 Drainage Clip - Wire Style				
1024709	420832	CONVATEC SOFT WIRE TIES (1X50PK) GB	768455OST0016FA	37502
DS40-279 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
1021258	125172	C/HESIVE 2+ CVX INS 25/38MM (1X5PK) SE	768455OST0018FE	47658

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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
DS40-280 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

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1189356	175510	S/CARE S2 BELT (1X1PK) CEE	768455OST0022F5	62951
TP12-022 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
TP21-031 Diamonds™ gelling and odour control Sachets				
1706529	420791	DIAMONDS ODOR CTRL TR105JAR (1X100 JAR)	768455OST0019FG	A108099
1706530	420792	DIAMONDS ODOR CTRL TR105 1X5PK	768455OST0019FG	A108099
1729196	420793	ESENTA DIAMONDS SACHETS (1X100JAR) INT	768455OST0019FG	A108099

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Revision History

Rev No	Date	Comment	Author
1	20 Oct 2023	Initial issue of combined DoC for MDR_OSTTF_003	Geraint Lewis