	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


One Piece Ileostomy Pouch Plus Minus DS10-049


Technical Documentation MDR OSTTF 005


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

We hereby declare that the mentioned product/ attached list of product 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 CH52NU United Kingdom 01244 584000
SRN:	GB-MF-000001770
Authorized Representative:	Unomedical A/S Aaholmvej 1-3, Osted, 4320 Lejre Denmark
Product Name:	One Piece Ileostomy Pouch Plus Minus
GMDN Code and Title:	31075 - One-piece intestinal ostomy bag, open-ended
CND nomenclature:	A100102 - ILEOSTOMY BAGS
Basic UDI-DI:	Refer to List of Product Codes attached
Identification of the device(s) concerned:	Refer to List of Product Codes attached
Catalogue Number:	Refer to List of Product Codes attached
Intended purpose:	Intended for the management of the stomal output
Risk Classification:	Class I as per Rule 1 in Annex VIII

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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
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: Gary Barrett</p>  <p>Signature:</p> <p>Vice President, Regulatory Affairs</p> <p>Place of Issue: Deeside., Flintshire</p> <p>Date: June 11 2021</p>

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List of Product Codes

Product ICC	SAP Codes	Trade Name	Basic UDI-DI
175523	1021692	ILEODRESS PCH DRN STD TAN 19MM 1X10NL/GB	768455OST0038FL
175524	1021693	ILEODRESS PCH DRN STD TAN 25MM 1X10NL/GB	768455OST0038FL
175525	1021694	ILEODRESS PCH DRN STD TAN 32MM 1X10NL/GB	768455OST0038FL
175526	1021695	ILEODRESS PCH DRN STD TAN 38MM 1X10NL/GB	768455OST0038FL
175527	1021696	ILEODRESS PCH DRN STD TAN 45MM 1X10NL/GB	768455OST0038FL
175528	1021697	ILEODRESS PCH DRN STD TAN 50MM 1X10NL/GB	768455OST0038FL
175530	1021699	ILEODRESS PCH DRN STD CLR 19MM 1X10NL/GB	768455OST0038FL
020922	1021868	L/ONE PCH DRN PAED CLR (1X15PK) GB	768455OST0038FL
020922	1021869	STOMADRESS PCH DRN PAED CLR (1X15PK) DE	768455OST0038FL
020922	1021871	ILEODRESS PCH DRN PAED MINI CLR (1X15)SE	768455OST0038FL
175516	1024626	ILEODRESS+ PCH DRN SM TAN 19MM(1X10PK)GB	768455OST0038FL
175523	1024635	STOMADRESS+ PCH DRN STD TAN 19MM(1X10)DE	768455OST0038FL
175523	1024636	ILEODRESS+ PCH DRN STD TAN 19MM (1X10)IT	768455OST0038FL
175523	1024638	ILEODRESS+ PCH DRN STD TAN 19MM (1X10)SE	768455OST0038FL
175525	1024646	ILEODRESS+ PCH DRN STD TAN 32MM (1X10)SE	768455OST0038FL
175530	1024661	STOMADRESS+ PCH DRN STD CLR 19MM(1X10)DE	768455OST0038FL
175533	1024669	ILEODRESS+ PCH DRN STD CLR 38MM (1X10)GB	768455OST0038FL
020922	1029183	ILEODRESS PCH DRA CLR (1X15PK) IT	768455OST0038FL
175523	1051989	STOMADRS 1PC DRN STD TAN+/-19MM(1X10)EEU	768455OST0038FL
175526	1052032	STOMADRS 1PC DRN STD TAN+/-38MM(1X10)EEU	768455OST0038FL
175527	1052033	STOMADRS 1PC DRN STD TAN+/-45MM(1X10)EEU	768455OST0038FL
175528	1052034	STOMADRS 1PC DRN STD TAN+/-50MM(1X10)EEU	768455OST0038FL
175529	1052035	STOMADRS 1PC DRN STD TAN+/-64MM(1X10)EEU	768455OST0038FL
175530	1052036	STOMADRS 1PC DRN STD CLR+/-19MM(1X10)EEU	768455OST0038FL
020922	1076306	STOMADRESS PCH DRN PAED CLR (1X15PK) EEU	768455OST0038FL
650816	1103599	ILEOHESIVE+ PCH DRN STD TAN 19MM(1X30)ES	768455OST0038FL
650817	1103600	ILEOHESIVE+ PCH DRN STD CLR 19MM(1X30)ES	768455OST0038FL
650816	1163323	ILEOHESIVE+ PCH DRN STD TAN 19MM(1X30)PT	768455OST0038FL
420590	1701952	STOMADRS DRNSTDTAN19MM NFLXTAIL(1X30)INT	768455OST0038FL
420591	1701953	STOMADRS DRNSTDCLR19MM NFLXTAIL(1X30)INT	768455OST0038FL