	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


Advanced One Piece Urostomy Pouch with Fold Up Tap DS10-189 Technical Documentation MDR OSTTF 007


This Declaration of Conformity is issued under the sole responsibility of the 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
SRN:	GB-MF-000001770
Authorized Representative:	Unomedical A/S Aaholmvej 1-3, Osted, 4320, Lejre Denmark
Product Name:	Advanced One Piece Urostomy Pouch with Fold Up Tap
GMDN Code and Title:	31068 – One-piece Urostomy Bag
Basic UDI-DI:	768455OST0003EZ
Identification of the device(s) concerned:	Refer to Product Range Table
Catalogue Number:	Refer to Product Range Table
Intended purpose:	Intended for management of 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: May 20 2021</p>

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List of Products

ICC Code	SAP Code	Product Description
401232	1167456	ESTEEM PCH URO STD CLR FUT 13MM (1X10) IT
	1172291	ESTEEM PCH URO STD CLR FUT 13MM(1X10)EEU
	1172559	ESTEEM PCH URO STD CLR FUT 13MM (1X10)DE
	1173720	ESTEEM PCH URO STD CLR FUT 13MM(1X10)SCN
	1177963	ESTEEM PCH URO STD CLR FUT13MM1X10 GB/NL
401233	1167493	ESTEEM PCH URO STD TAN FUT 13MM (1X10) IT
	1172292	ESTEEM PCH URO STD TAN FUT 13MM(1X10)EEU
	1172555	ESTEEM PCH URO STD TAN FUT13MM1X10 GB/NL
	1172574	ESTEEM PCH URO STD TAN FUT 13MM (1X10)DE
	1173721	ESTEEM PCH URO STD TAN FUT 13MM(1X10)SCN
401234	1167500	ESTEEM PCH URO SM CLR FUT 13MM (1X10) IT
	1172068	ESTEEM PCH URO SM CLR FUT 13MM 1X10NL/GB
	1172581	ESTEEM PCH URO SM CLR FUT 13MM (1X10) DE
401235	1172563	ESTEEM PCH URO SM TAN FUT 13MM1X10 GB/NL
	1172592	ESTEEM PCH URO SM TAN FUT 13MM (1X10) DE
	1173726	ESTEEM PCH URO SM TAN FUT 13MM (1X10)SCN
401236	1172063	ESTEEM PCH URO STDCLR FUT 20MM (1X10) NL/GB
401237	1172556	ESTEEM PCH URO STD TAN FUT20MM1X10 GB/NL
	1173722	ESTEEM PCH URO STD TAN FUT 20MM(1X10)SCN
401240	1172064	ESTEEM PCH URO STDCLR FUT 25MM (1X10) NL/GB
401241	1172237	ESTEEM PCH URO STD TAN FUT 25MM(1X10)EEU
	1172557	ESTEEM PCH URO STD TAN FUT25MM1X10 GB/NL
	1173723	ESTEEM PCH URO STD TAN FUT 25MM(1X10)SCN
401242	1172070	ESTEEM PCH URO SM CLR FUT 25MM 1X10NL/GB
401243	1172566	ESTEEM PCH URO SM TAN FUT 25MM1X10 GB/NL
401244	1172065	ESTEEM PCH URO STDCLR FUT 30MM (1X10) NL/GB
401245	1172238	ESTEEM PCH URO STD TAN FUT 30MM(1X10)EEU
	1172558	ESTEEM PCH URO STD TAN FUT30MM1X10 GB/NL



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ICC Code	SAP Code	Product Description
	1173724	ESTEEM PCH URO STD TAN FUT 30MM(1X10)SCN
401246	1172081	ESTEEM PCH URO SM CLR FUT 30MM 1X10 NL/GB
401248	1172066	ESTEEM PCH URO STDCLR FUT 35MM (1X10) NL/GB
401249	1172560	ESTEEM PCH URO STD TAN FUT35MM 1X10 GB/NL
401250	1172082	ESTEEM PCH URO SM CLR FUT 35MM 1X10 NL/GB
410300	1172876	ESTEEM PCH URO STD CLR FUT 13MM (1X30) FR
410301	1172877	ESTEEM PCH URO STD TAN FUT 13MM (1X30) FR
410304	1172565	ESTEEM PCH URO STD CLR FUT 20MM (1X30) FR
410308	1172567	ESTEEM PCH URO STD CLR FUT 25MM (1X30) FR
410312	1172569	ESTEEM PCH URO STD CLR FUT 30MM (1X30) FR
410316	1172571	ESTEEM PCH URO STD CLR FUT 35MM (1X30) FR
410320	1172572	ESTEEM PCH URO STD CLR FUT 40MM (1X30) FR