	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


### APS One Piece Closed End Pouches DS10-256


### 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:	APS One Piece Closed End Pouches
GMDN Code and Title:	31066 - One-piece intestinal ostomy bag, closed-ended
CND nomenclature:	A100101 - COLOSTOMY BAGS, ONE-PIECE 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><b>Name:</b> Gary Barrett</p> <p><b>Signature:</b> </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
416700	1703734	ESTEEM+ PCH CLDSTDCLRWF60/70MM(1X30) EUR	768455OST0038FL
416702	1703741	ESTEEM+ PCH CLD SMTANWF60/70MM(1X30) EUR	768455OST0038FL
416705	1703742	ESTEEM+ PCH CLD SM TAN WF 25MM(1X30) EUR	768455OST0038FL
416708	1703743	ESTEEM+ PCH CLD WF SMTAN 30MM (1X30) EUR	768455OST0038FL
416711	1703744	ESTEEM+ PCH CLD SM TANWF 35MM (1X30) EUR	768455OST0038FL
416714	1703745	ESTEEM+ PCH CLD SM TAN WF 40MM(1X30) EUR	768455OST0038FL
416703	1703781	ESTEEM+ PCH CLD WF STDCLR 25MM(1X30) EUR	768455OST0038FL
416706	1703782	ESTEEM+ PCH CLD WF STDCLR 30MM(1X30) EUR	768455OST0038FL
416707	1703783	ESTEEM+ PCH CLD WF STD TAN 30MM(1X30) EUR	768455OST0038FL
416709	1703784	ESTEEM+ PCH CLD WF STD CLR 35MM(1X30)EUR	768455OST0038FL
416710	1703785	ESTEEM+ PCH CLD WF STD TAN 35MM(1X30) EUR	768455OST0038FL
416701	1703789	ESTEEM+ PCHCLDSTD TANWF60/70MM (1X30) EUR	768455OST0038FL
416715	1703792	ESTEEM+ PCH CLD WF STD TAN 50MM(1X30) EUR	768455OST0038FL
416713	1703793	ESTEEM+ PCH CLD WF STD TAN 40MM(1X30) EUR	768455OST0038FL
416712	1703794	ESTEEM+ PCH CLD WF STDCLR 40MM(1X30) EUR	768455OST0038FL
416704	1703796	ESTEEM+ PCH CLD WF STD TAN 25MM(1X30) EUR	768455OST0038FL
420497	1703846	ESTEEM+ PCH CLDWFSTDCLRXCOL30MM 1X30 EUR	768455OST0038FL
420499	1703847	ESTEEM+ PCHCLDWFSTD TANXCOL 30MM 1X30 EUR	768455OST0038FL
420500	1703848	ESTEEM+ PCHCLDWFSTDCLRXCOL 35MM 1X30 EUR	768455OST0038FL
420502	1703849	ESTEEM+ PCHCLDWFSTD TANXCOL 35MM 1X30 EUR	768455OST0038FL
420503	1703850	ESTEEM+ PCHCLDWFSTDCLRXCOL 40MM 1X30 EUR	768455OST0038FL
420505	1703851	ESTEEM+ PCHCLDWFSTD TANXCOL 40MM 1X30 EUR	768455OST0038FL
420506	1703852	ESTEEM+ PCHCLDWFSTD TANXCOL 50MM 1X30 EUR	768455OST0038FL
420507	1703853	ESTEEM+ PCHCLDWFSTDCLRXCOL60/70MM1X30EUR	768455OST0038FL
420508	1703854	ESTEEM+ PCHCLDWFSTANXCOL60/70MM1X30 EUR	768455OST0038FL
420509	1703855	ESTEEM+ PCHCLDWFSTD TANXCOL60/70MM1X30EUR	768455OST0038FL
420510	1703856	ESTEEM+ PCH WF CLD STD CLR 25MM 1X50 EUR	768455OST0038FL
420511	1703857	ESTEEM+ PCH WF CLD SM TAN 25MM 1X50 EUR	768455OST0038FL
420512	1703858	ESTEEM+ PCH WF CLD STD TAN 25MM 1X50 EUR	768455OST0038FL
420514	1703860	ESTEEM+ PCH WF CLD SM TAN 30MM 1X50 EUR	768455OST0038FL
420515	1703861	ESTEEM+ PCH WF CLD STD TAN 30MM 1X50 EUR	768455OST0038FL
420516	1703862	ESTEEM+ PCH WF CLD STD CLR 35MM 1X50 EUR	768455OST0038FL
420517	1703863	ESTEEM+ PCH WF CLD SM TAN 35MM 1X50 EUR	768455OST0038FL
420518	1703864	ESTEEM+ PCH WF CLD STD TAN 35MM 1X50 EUR	768455OST0038FL
420519	1703865	ESTEEM+ PCH WF CLD STD CLR 40MM 1X50 EUR	768455OST0038FL
420520	1703866	ESTEEM+ PCH WF CLD SM TAN 40MM 1X50 EUR	768455OST0038FL
420521	1703867	ESTEEM+ PCH WF CLD STD TAN 40MM 1X50 EUR	768455OST0038FL
420522	1703868	ESTEEM+ PCH WF CLD STD TAN 50MM 1X50 EUR	768455OST0038FL
420523	1703869	ESTEEM+ PCHWFCLDSTD CLR 60/70MM 1X50 EUR	768455OST0038FL
420524	1703870	ESTEEM+ PCHWFCLD SM TAN 60/70MM 1X50 EUR	768455OST0038FL



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Product ICC	SAP Codes	Trade Name	Basic UDI-DI
420525	1703871	ESTEEM+ PCHWFCLDSTD TAN 60/70MM 1X50 EUR	768455OST0038FL
421686	1715545	ESTEEM+PCH CLD STD WIN WF 60/70 1X30 EUR	768455OST0038FL
421687	1715546	ESTEEM+PCH CLD STD WIN WF 25MM 1X30 EUR	768455OST0038FL
421688	1715547	ESTEEM+PCH CLD STD WIN WF 30MM 1X30 EUR	768455OST0038FL
421689	1715548	ESTEEM+PCH CLD STD WIN WF 35MM 1X30 EUR	768455OST0038FL
421816	1718342	ESTEEM+PCH CLD SM WIN WF20/70(1X30PK)EUR	768455OST0038FL
421817	1718344	ESTEEM+PCH CLD SM WIN WF 25MM(1X30PK)EUR	768455OST0038FL
421818	1718346	ESTEEM+PCH CLD SM WIN WF 30MM(1X30PK)EUR	768455OST0038FL
421819	1718348	ESTEEM+PCH CLD SM WIN WF 35MM(1X30PK)EUR	768455OST0038FL
421820	1718350	ESTEEM+PCH CLD SM WIN WF 40MM(1X30PK)EUR	768455OST0038FL
421822	1718356	ESTEEM+PCH CLD STD WIN WF 40MM (1X30)EUR	768455OST0038FL
421823	1718358	ESTEEM+PCH CLD STD WIN WF 50MM (1X30)EUR	768455OST0038FL
421824	1718360	ESTEEM+PCH CLD STD WIN WF 60MM (1X30)EUR	768455OST0038FL
421825	1718362	ESTEEM+PCH CLD LG WIN WF20/70MM(1X30)EUR	768455OST0038FL
421826	1718364	ESTEEM+PCH CLD LG WIN WF 25MM (1X30)EUR	768455OST0038FL
421827	1718366	ESTEEM+PCH CLD LG WIN WF 30MM (1X30)EUR	768455OST0038FL
421828	1718368	ESTEEM+PCH CLD LG WIN WF 35MM (1X30)EUR	768455OST0038FL
421829	1718370	ESTEEM+PCH CLD LG WIN WF 40MM (1X30)EUR	768455OST0038FL
421830	1718372	ESTEEM+PCH CLD LG WIN WF 50MM (1X30)EUR	768455OST0038FL
421831	1718374	ESTEEM+PCH CLD LG CLR WF20/70MM(1X30)EUR	768455OST0038FL
421832	1718376	ESTEEM+PCH CLD LG CLRWF 25MM (1X30)EUR	768455OST0038FL
421833	1718378	ESTEEM+PCH CLD LG CLR WF 30MM (1X30)EUR	768455OST0038FL
421834	1718380	ESTEEM+PCH CLD LG CLR WF 35MM (1X30)EUR	768455OST0038FL
421835	1718382	ESTEEM+PCH CLD LG CLR WF 40MM (1X30)EUR	768455OST0038FL
421836	1718384	ESTEEM+PCH CLD LG CLR WF 50MM (1X30)EUR	768455OST0038FL
422190	1721439	ESTEEM+PCHCLD SM WIN WFXCOL20/70(1X30)ES	768455OST0038FL
422191	1721440	ESTEEM+PCHCLDSTD WIN WFXCOL20/70(1X30)ES	768455OST0038FL
422194	1721443	ESTEEM+PCHCLDSTD WIN WFXCOL 35MM(1X30)ES	768455OST0038FL
422195	1721444	ESTEEM+PCHCLDSTD WIN WFXCOL 40MM(1X30)ES	768455OST0038FL
422196	1721445	ESTEEM+PCHCLDSTD WIN WFXCOL 50MM(1X30)ES	768455OST0038FL
422198	1721447	ESTEEM+PCHCLDLG WINWFXCOL20/70MM(1X30)ES	768455OST0038FL
422201	1721450	ESTEEM+PCHCLD LG WIN WFXCOL 35MM(1X30)ES	768455OST0038FL
422202	1721451	ESTEEM+PCHCLD LG WIN WFXCOL 40MM(1X30)ES	768455OST0038FL
422203	1721452	ESTEEM+PCHCLD LG WIN WFXCOL 50MM(1X30)ES	768455OST0038FL
422454	1726899	ESTEEM+PCHCLD SM WIN WF EWC 25MM(1X30)ES	768455OST0038FL
422456	1726902	ESTEEM+PCHCLD SM WIN WF EWC 35MM(1X30)ES	768455OST0038FL
422457	1726903	ESTEEM+PCHCLD SM WIN WF EWC 40MM(1X30)ES	768455OST0038FL