	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 Esteem Drainable Pouch with Clipless Closure DS10-261


### 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 Esteem Drainable Pouch with Clipless Closure
GMDN Code and Title:	31075 - One-piece intestinal ostomy bag, open-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>

	Effective Date:	24-Jul-2020	CR:	CR-040524
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**List of Product Codes**

Product ICC	SAP Codes	Trade Name	Basic UDI-DI
416737	1703623	ESTEEM+PCHDRNWFINVISISTDTAN40MM(1X10)EUR	768455OST0038FL
416733	1703650	ESTEEM+PCHDRNWFINVISISTDTAN35MM(1X10)EUR	768455OST0038FL
416732	1703655	ESTEEM+PCHDRNWFINVISISTDCLR35MM(1X10)EUR	768455OST0038FL
416729	1703656	ESTEEM+ PCHDRNWFINVISITAN 30MM(1X10) EUR	768455OST0038FL
416728	1703657	ESTEEM+PCHDRNWFINVISISTDCLR30MM(1X10)EUR	768455OST0038FL
416725	1703659	ESTEEM+PCHDRNWFINVISISTDTAN25MM(1X10)EUR	768455OST0038FL
416724	1703660	ESTEEM+PCHDRNWFINVISISTDCLR25MM(1X10)EUR	768455OST0038FL
416721	1703662	ESTEEM+PCHDRNW/INVISICLR60/70MM(1X10)EUR	768455OST0038FL
416719	1703663	ESTEEM+PCHDRNWFINVISITAN60/70MM(1X10)EUR	768455OST0038FL
416718	1703664	ESTEEM+PCHDRNWFINVISICLR60/70MM(1X10)EUR	768455OST0038FL
420288	1703671	ESTEEM+ PCH DRNWFINVISISTDTAN25MM 30 EUR	768455OST0038FL
420294	1703672	ESTEEM+ PCH DRNWFINVISISTDTAN30MM 30 EUR	768455OST0038FL
420306	1703673	ESTEEM+ PCH DRNWFINVISISTDTAN40MM 30 EUR	768455OST0038FL
420307	1703674	EST+PCHDRNWFINVISICTFSTDCLR60/70MM30 EUR	768455OST0038FL
420310	1703675	EST+PCHDRNWFINVISICTFSTDAN60/70MM30 EUR	768455OST0038FL
420318	1703680	ESTEEM+ PCH DRNWFINVISISTDCLR25MM 50 EUR	768455OST0038FL
420321	1703682	ESTEEM+ PCHDRNWF INVISISTDTAN25MM 50 EUR	768455OST0038FL
420325	1703687	ESTEEM+ PCH DRNWFINVISISTDCLR30MM 50 EUR	768455OST0038FL
420327	1703688	ESTEEM+ PCH DRNWFINVISISTDTAN30MM 50 EUR	768455OST0038FL
420330	1703691	ESTEEM+ PCH DRNWFINVISISTDCLR35MM 50 EUR	768455OST0038FL
420333	1703693	ESTEEM+ PCH DRNWFINVISISTDTAN35MM 50 EUR	768455OST0038FL
420337	1703697	ESTEEM+ PCH DRN WFINVISISTDCLR40MM50 EUR	768455OST0038FL
420339	1703698	ESTEEM+ PCH DRNWFINVISISTDTAN40MM 50 EUR	768455OST0038FL
420340	1703699	EST+ PCHDRNWFINVISICTFSTDCLR60/70MM50EUR	768455OST0038FL
420343	1703700	EST+ PCHDRNWFINVISICTFSTDAN60/70MM50EUR	768455OST0038FL
421858	1718409	ESTEEM+INVISI STD WIN WF20/70MM(1X10)EUR	768455OST0038FL
421859	1718410	ESTEEM+ INVISI STD WIN WF 25MM (1X10)EUR	768455OST0038FL
421860	1718411	ESTEEM+ INVISI STD WIN WF 30MM (1X10)EUR	768455OST0038FL
421862	1718412	ESTEEM+ INVISI STD WIN WF 40MM (1X10)EUR	768455OST0038FL
421861	1718460	ESTEEM+ INVISI STD WIN WF 35MM (1X10)EUR	768455OST0038FL
422231	1722009	ESTEEM+INVISI STD WIN WF 20/70MM(1X30)ES	768455OST0038FL
422232	1722010	ESTEEM+ INVISI STD WIN WF 25MM (1X30)EUR	768455OST0038FL
422233	1722011	ESTEEM+ INVISI STD WIN WF 30MM (1X30)EUR	768455OST0038FL
422234	1722012	ESTEEM+ INVISI STD WIN WF 35MM (1X30)EUR	768455OST0038FL
422235	1722013	ESTEEM+ INVISI STD WIN WF 40MM (1X30)EUR	768455OST0038FL
423386	1733585	ESTEEM+INVISI STD WIN WF20/70MM(1X30)FR	768455OST0038FL
423387	1733586	ESTEEM+ INVISI STD WIN WF 25MM (1X30)FR	768455OST0038FL
423388	1733587	ESTEEM+ INVISI STD WIN WF 30MM (1X30)FR	768455OST0038FL
423389	1733588	ESTEEM+ INVISI STD WIN WF 40MM (1X30)FR	768455OST0038FL
423390	1733589	ESTEEM+ INVISI STD WIN WF 35MM (1X30)FR	768455OST0038FL