	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 Clip DS10-260


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 Clip
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>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
421837	1718386	ESTEEM+DRN CLP SM TAN WF20/70MM(1X10)EUR	768455OST0038FL
421838	1718387	ESTEEM+DRN CLP STD TANWF20/70MM(1X10)EUR	768455OST0038FL
421839	1718388	ESTEEM+ DRN CLP STD TAN WF 25MM(1X10)EUR	768455OST0038FL
421840	1718389	ESTEEM+ DRN CLP STD TAN WF 30MM(1X10)EUR	768455OST0038FL
421841	1718390	ESTEEM+ DRN CLP STD TAN WF 35MM(1X10)EUR	768455OST0038FL
421842	1718392	ESTEEM+DRN CLP STD TAN WF 40MM(1X10)EUR	768455OST0038FL
421843	1718393	ESTEEM+ DRN CLP SM TAN WF 25MM(1X10) EUR	768455OST0038FL
421844	1718394	ESTEEM+ DRN CLP SM TAN WF 30MM(1X10) EUR	768455OST0038FL
421845	1718395	ESTEEM+ DRN CLP SM TAN WF 35MM(1X10) EUR	768455OST0038FL
421846	1718396	ESTEEM+ DRN CLP SM TAN WF 40MM(1X10) EUR	768455OST0038FL
421847	1718397	ESTEEM+DRN CLP SM CLRWF20/70MM(1X10)EUR	768455OST0038FL
421848	1718398	ESTEEM+DRN CLP STD CLRWF20/70MM(1X10)EUR	768455OST0038FL