	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 Post Operative Pouch With Clipless Closure DS10-265


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 Post Operative 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

	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		

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. CE MD 670405, issued by BSI Notified Body Number 2797 In accordance with Annex IX of this Regulation
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 26 2021</p>

	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		

List of Product Codes

Product ICC	SAP Codes	Trade Name	Basic UDI-DI
416908	1703791	ESTEEM+PCHDRNW/INVISISTDCLR100MM1X10EUR	768455OST0038FL
420344	1703802	ESTEEM+ PCH INVISISTDCLR PO 100MM 50 EUR	768455OST0038FL