EU Declaration of Conformity

One Piece Standard Fold-Over Urostomy Pouch DS10-062
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:	One Piece Standard Fold Over Urostomy Pouch
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

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:	**Name: Gary Barrett** **Signature:**  Vice President, Regulatory Affairs Place of Issue: Deeside., Flintshire Date: May 20 2021

List of Products

ICC Code	SAP Code	Product Description
064927	1023421	URODRESS PCH URO STD 19MM (1X10PK) GB
	1023422	STOMADRESS+ PCH URO STD 19MM (1X10PK) DE
	1023423	ACTIVE LIFE PCH URO STD 19MM (1X10PK) INT
	1023424	URODRESS PCH URO STD 19MM (1X10PK) IT
	1023426	URODRESS PCH URO STD 19MM (1X10PK) NL
	1076307	STOMADRESS+ PCH URO STD 19MM (1X10PK) EEU
064928	1023428	URODRESS PCH URO STD 25MM (1X10PK) GB
	1023429	STOMADRESS+ PCH URO STD 25MM (1X10PK) DE
	1023430	ACTIVE LIFE PCH 1PC URO STD 25MM 1X10INT
	1023431	URODRESS PCH URO STD 25MM (1X10PK) IT
	1076308	STOMADRESS+ PCH URO STD 25MM (1X10PK) EEU
064929	1023432	URODRESS PCH URO STD 32MM (1X10PK) GB
	1023433	STOMADRESS+ PCH URO STD 32MM (1X10PK) DE
	1023435	URODRESS PCH URO STD 32MM (1X10PK) IT
	1076309	STOMADRESS+ PCH URO STD 32MM (1X10PK) EEU
064930	1023436	URODRESS PCH URO STD 38MM (1X10PK) GB
	1023439	URODRESS PCH URO STD 38MM (1X10PK) IT
	1023438	ACTIVE LIFE PCH 1PC URO STD 38MM (1X10PK) INT
	1076310	STOMADRESS+ PCH URO STD 38MM (1X10PK) EEU
064931	1023440	URODRESS PCH URO STD 45MM (1X10PK) GB
	1023443	URODRESS PCH URO STD 45MM (1X10PK) IT
	1076471	STOMADRESS+ PCH URO STD 45MM (1X10PK) EEU
064994	1023450	URODRESS PCH 1PC URO STD 19MM (1X15PK)BE