EU Declaration of Conformity

System 2 Security Belt PR40-280

Technical Documentation MDR_OSTTF_003

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:	• System 2 Security Belt • Ostomy Appliance Belt • Appliance Belt • Ostomy Belt
GMDN Code and Title:	62951 Ostomy appliance belt
CND nomenclature:	A108006 Supporting Belt
Basic UDI-DI:	768455OST0022F5
Identification of the device(s) concerned:	Full List of Product Codes or Ref. to Product Range Table
Catalogue Number:	Full List of Product Codes or Ref. to Product Range Table
Intended purpose:	System 2 Security Belts are intended to provide extra security for ostomy systems by securing the ostomy pouch around the user's waist.
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 25 2021

List of Products

ICC Code	SAP Code	Product Description
175507	1021685	C/HESIVE 2S BELT 42" (1X1PK) BE
175507	1021686	C/HESIVE 2+ BELT 42" (1X1PK) SE
175510	1024619	C/HESIVE SYS BELT (1X1PK) FR
175510	1024620	S/CARE S2 BELT (1X1PK) GB
175510	1024621	C/HESIVE SYS BELT (1X1PK) DE
175510	1024622	S/HESIVE SISTEMA 2 BELT (1X1PK) IT
175510	1024624	C/HESIVE SYS BELT (1X1PK) NL
175510	1115621	S2 BELT COLO/ILEO/URO (1X1PK) ES
175510	1189356	S/CARE S2 BELT (1X1PK) CEE