EU Declaration of Conformity

System 3 Plus Stoma Cap DS10-069

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:	Colodress Plus Stomadress Plus Stoma Cap
GMDN Code and Title:	31066 One-piece intestinal ostomy bag, closed ended
CND nomenclature:	A100205 Two-Pieces Ostomy Devices, Caps
Basic UDI-DI:	768455OST0021F3
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:	ConvaTec stoma caps are intended to be used to manage of stomal output for short periods of time or following irrigation.
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:** Garry Barrett  **Signature:** Vice President, Regulatory Affairs Place of Issue: Deeside., Flintshire Date: May 25 2021

List of Products

ICC Code	SAP Code	Product Description
175611	1021701	IRIDRESS STOMACAP 1PC (1X30PK) FR
175611	1024684	COLODRESS+ STOMACAP (1X30PK) BE
175611	1024685	COLODRESS+ STOMACAP (1X30PK) GB
175611	1024686	STOMADRESS+ STOMACAP (1X30PK) DE
175611	1024687	STOMADRESS+ STOMACAP (1X30PK) IT
175611	1024689	STOMADRESS+ STOMACAP (1X30PK) SE
175611	1189357	STOMADRESS+ STOMACAP (1X30PK) EEU