EU Declaration of Conformity

Stomahesive® Paste Protective Skin Barrier PR/DL10-001 (Stomahesive® Paste) Technical Documentation MDR_OSTTF_002

This Declaration of Conformity is issued under the sole responsibility of the ConvaTec Limited.

We hereby declare that the mentioned product/ attached list of products 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:	Stomahesive® Paste
GMDN Code and Title:	46207 - Peristomal/Periwound Dressing
CND nomenclature:	A108001 - anello/lunetta/piastra per cute peristomale Protective paste/gel for peristomal skin
Basic UDI-DI:	768455OST0014F6
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:	Intended to protect exposed skin between the base of the stoma and the opening in the wafer, and as filler for skin folds and uneven skin surface.
Risk Classification:	Class I as per Rule I 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 Harmonised 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:	**Name:** Gary Barrett **Signature:** DocuSigned by: Gary Barrett Signer Name: Gary Barrett Signing Reason: I approve this document Signing Time: May 6, 2021 | 12:53:30 PM BST A40D1F939D7141E182BD080455A1B09E Vice President, Regulatory Affairs Place of Issue: Deeside., Flintshire Date: May 6, 2021

List of Products

ICC Code	SAP Code	Product Description
183910	1000750	STOMAHESIVE PASTE (1TUBEX60G) IT
183910	1000745	STOMAHESIVE PASTE (1TUBEX60G) FR
183910	1000751	STOMAHESIVE PASTE (1TUBEX60G) ES
183910	1000746	STOMAHESIVE PASTE (1TUBEX60G) DE
183910	1000749	STOMAHESIVE PASTE (1TUBEX60G) BE
183910	1231164	STOMAHESIVE PASTE (1TUBEX56.7G) INT
183910	1000747	STOMAHESIVE PASTE (1TUBEX60G) SCN
183910	1052383	STOMAHESIVE PASTE (1TUBEX60G) CEU
183910	1000753	STOMAHESIVE PASTE (1TUBEX60G) GB