EU Declaration of Conformity

Diamonds™ gelling and odour control Sachets_TP21-031

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:	ConvaTec Diamonds™ gelling and odour control Sachets
GMDN Code and Title:	58116 Liquid excrement solidifier
CND nomenclature:	A108099 Ostomy Accessories Devices -Other
Basic UDI-DI:	768455OST0019FG
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 Diamonds™ are intended to gel the semi-formed to liquid contents of an ileostomy or colostomy pouch, or a faecal management system collection bag, and to reduce or eliminate unwanted odours and excess flatus.
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
420791	1706529	DIAMONDS ODOR CTRL TR105JAR (1X100 JAR)
420792	1706530	DIAMONDS ODOR CTRL TR105 1X5PK
420791	1729196	ESENTA DIAMONDS SACHETS (1X100JAR) INT