EU Declaration of Conformity

Esenta™ Sting Free Adhesive Remover Spray (150ml)

Technical Documentation MDR_OSTTF_019

This Declaration of Conformity is issued under the sole responsibility of 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 01244 584000
SRN:	GB-MF-000001770
Authorized Representative:	Unomedical A/S Aaholmvej 1-3, Osted, 4320 Lejre Denmark
Product Name:	Refer to Product Description in list of products
GMDN Code and Title:	Refer to GMDN Code and Title in list of products
CND nomenclature:	Refer to CND Nomenclature in list of products
Basic UDI-DI:	Refer to Basic UDI-DI in list of products
Identification of the device(s) concerned:	Refer to Product Description in list of products
Catalogue Number:	Refer to ICC Code in list of products
Intended purpose:	Refer to intended purpose in list of products
Risk Classification:	Class Is as per Rule 13 in Annex VIII

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Conformity Assessment Route:	Annex IX of EU Medical Device Regulation (EU) 2017/745
Relevant Harmonized Standards:	EN ISO 13485:2016, EN ISO 13485:2016/A11:2021: Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 14971:2019, EN ISO 14971:2019/A11:2021: Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 15223-1:2021: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) EN ISO 11607-1:2020+A11:2022 Packaging for terminally sterilized medical devices — Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020+A11:2022 Packaging for terminally sterilized medical devices — Validation requirements for forming, sealing and assembly processes
References to any CS:	Not Applicable
Identification of Notified Body:	BSI Group The Netherlands B.V. Say Building John.M. Keynesplein 9 1066 EP Amsterdam Netherlands 2797
Identification of the Certificate(s):	EC Quality Management System Certificate No. MD 670405, issued by BSI.

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Identification of the person authorized to sign on behalf of Legal Manufacturer:	**Name:** Courtney Smith DocuSigned by: Courtney Smith Signer Name: Courtney Smith Signing Reason: I approve this document Signing Time: May 17, 2023 | 12:44:40 PM BST **Signature:** 18C584297FF34C80A5D3283D05D64343 Sr. Director, Regulatory Affairs Ostomy Place of Issue: Deeside., Flintshire Date: May 17, 2023

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List of Product Codes

ICC Code	REF Code	SAP Code	Product Description	Intended Purpose	GMDN Code and Title	Basic UDI-DI	CND Nomenclature	Specification Number
423290	N/A	1732450	Esenta™ Sting Free Adhesive Remover Spray 150ml	Removal of adhesives, dressings and appliances from skin.	60494-Patient medical adhesive remover	768455OST0029FK	A108005-DEVICES FOR THE REMOVAL OF ADHESIVES FROM THE PERISTOMAL SKIN	TP21-056

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