EU Declaration of Conformity

Esenta™ Sting Free Adhesive Remover Products

Technical Documentation MDR_OSTTF_016

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 List of Product Codes attached
GMDN Code and Title:	60494- Patient medical adhesive remover
CND nomenclature:	A108005- devices for the removal of adhesives from the peristomal skin
Basic UDI-DI:	Refer to List of Product Codes attached
Identification of the device(s) concerned:	Refer to List of Product Codes attached
Catalogue Number:	Refer to List of Product Codes attached
Intended purpose:	Removal of adhesives, dressings and appliances from skin
Risk Classification:	Esenta™ Sting Free Adhesive Remover Spray: Class I as per Rule 13 in Annex VIII Esenta™ Sting Free Adhesive Remover wipes (25 and 30 pack): Class I as per Rule 1 in Annex VIII

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

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: Aug 17 2021

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

List of Product Codes

Product ICC	Product SAP	Trade Name	Basic UDI-DI
423289	1729206	Esenta™ Sting Free Adhesive Remover Spray 50ml	768455OST0034FC
423391	1733699	Esenta™ Sting Free Adhesive Remover wipes (25 pack)	768455OST0028FH
423281	1729194	Esenta™ Sting Free Adhesive Remover wipes (30 pack)	768455OST0028FH

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

Revision History

Rev no	***Date***	***Comment***	***Author***
1.0	17/08/2021	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Sana Ashraf

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.