EU Declaration of Conformity

Esenta™ Sting Free Skin Barrier Products

Technical Documentation MDR_OSTTF_017

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:	58978- Synthetic-polymer liquid barrier dressing, non-sterile
CND nomenclature:	A108004- protective films / sprays for 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:	Protection of skin from the damage associated with body waste, enzymes and adhesives.
Risk Classification:	Esenta™ Sting Free Skin Barrier Spray 50ml: Class I as per Rule 13 in Annex VIII Esenta™ Sting Free Skin Barrier Pump Spray 28ml and Wipes (25 and 30 pack): Class I as per Rule 1 in Annex VIII

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Conformity Assessment Route:	Annex II and III 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)
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:** Courtney Smith **Signature:** DocuSigned by: Courtney Smith Signer Name: Courtney Smith Signing Reason: I approve this document Signing Time: Apr 13, 2023 | 12:35:31 PM BST 18C584297FF34C80A5D3283D05D64343 Sr. Director, Regulatory Affairs Ostomy Care & Continence Care Place of Issue: Deeside., Flintshire Date: Apr 13, 2023

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List of Product Codes

Product ICC	Product SAP	Trade Name	Basic UDI-DI
423288	1729205	Esenta™ Sting Free Skin Barrier Spray 50ml	768455OST0026FD
	1738810	Esenta™ Sting Free Skin Barrier Spray 50ml	
423286	1729201	Esenta™ Sting Free Skin Barrier Pump Spray 28ml	768455OST0027FF
423392	1733700	Esenta™ Sting Free Skin Barrier Wipes (1x25pack)	768455OST0025FB
423282	1729195	Esenta™ Sting Free Skin Barrier Wipes (1x30pack)	768455OST0025FB
	1738809	Esenta™ Sting Free Skin Barrier Wipes (1x30pack)	

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Revision History

Rev no	***Date***	***Comment***	***Author***
1.0	18/08/2021	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Sana Ashraf
2.0	11/04/2023	List of product codes has been updated to include SAP codes 1738810, 1738809 and their product descriptions. In addition, the 'Relevant Harmonized Standards', list has been updated.	Michael Chitiyo

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