# 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.

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|---|---|
| Legal Manufacturer: | ConvaTec Limited<br>First Avenue, Deeside Industrial Park, Deeside, Flintshire<br>CH52NU<br>United Kingdom<br>01244 584000 |
| SRN: | GB-MF-000001770 |
| Authorized Representative: | Unomedical A/S<br>Aaholmvej 1-3, Osted, 4320 Lejre<br>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<br>Esenta™ Sting Free Adhesive Remover 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)<br>EN ISO 14971:2019, EN ISO 14971:2019/A11:2021: Medical devices - Application of risk management to medical devices (ISO 14971:2019)<br>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<br>**Signature:** DocuSigned by: Courtney Smith<br>Signer Name: Courtney Smith<br>Signing Reason: I approve this document<br>Signing Time: Apr 13, 2023 \| 12:35:46 PM BST<br>18C584297FF34C80A5D3283D05D64343<br>Sr. Director, Regulatory Affairs Ostomy Care & Continence Care<br>Place of Issue: Deeside., Flintshire<br>Date: Apr 13, 2023 |



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## List of Product Codes

| Product ICC | Product SAP | Trade Name | Basic UDI-DI |
|---|---|---|---|
| 423289 | 1729206 | Esenta™ Sting Free Adhesive Remover Spray 50ml | 768455OST0034FC |
| | 1738811 | Esenta™ Sting Free Adhesive Remover Spray 50ml | |
| 423391 | 1733699 | Esenta™ Sting Free Adhesive Remover wipes (25 pack) | 768455OST0028FH |
| 423281 | 1729194 | Esenta™ Sting Free Adhesive Remover wipes (30 pack) | 768455OST0028FH |
| | 1738808 | Esenta™ Sting Free Adhesive Remover wipes (30 pack) | |



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