# EU Declaration of Conformity

## ConvaCare™ and Sensi-Care™TP21-027 Adhesive Remover Sprays

## Technical Documentation MDR_OSTTF_012

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.

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| Legal Manufacturer: | ConvaTec Limited<br>First Avenue, Deeside Industrial Park, Deeside, Flintshire<br>CH52NU<br>United Kingdom |
| SRN: | GB-MF-000001770 |
| Authorized Representative: | Unomedical A/S<br>Aaholmvej 1-3, Osted, 4320, Lejre<br>Denmark |
| Product Name: | Niltac™ Medical Adhesive Remover sprays (non-sterile)<br><br>Sensi-Care™ Medical Adhesive Remover sprays (non-sterile) |
| GMDN Code and Title: | GMDN 60494<br>A liquid solvent intended for removal of medical adhesive/adhered devices (e.g., residual adhesive, adhesive tape, ostomy devices) from a patient's skin. After application, this device cannot be reused. |
| Basic UDI-DI: | 768455OST0034FC. |
| Identification of the device(s) concerned: | Refer to Product Range Table |
| Catalogue Number: | Refer to Product Range Table |
| Intended purpose: | Atraumatic removal of medical adhesives, wound dressings and appliances. |
| Risk Classification: | 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: | 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**<br>**Signature:**  <br>Vice President, Regulatory Affairs<br>Place of Issue: Deeside., Flintshire<br>Date: May 26 2021 |

## List of Products

| ICC Code | SAP Code | Product Description |
|---|---|---|
| 420787 | 1706525 | ConvaTec Niltac™ Sting Free Medical Adhesive Remover, 50 ml Spray |
| 413499 | 1708246 | Sensi-Care™ Sting Free Adhesive Releaser Spray |