

EC Declaration of Conformity
Technical File {WTTF-007/ PR/DL20-050}

Manufacturer Name: ConvaTec Limited,
Address: First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
United Kingdom

This Declaration is made under the sole responsibility of the manufacturer, ConvaTec Limited, who herewith declares that the attached list of mentioned product conforms to the applicable essential requirements and provisions of Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC) concerning medical devices.

| | |
|---|---|
| Product Name | Trade/ Brand Name(s): AQUACEL with Strengthening Fiber, AQUACEL WSF |
| Product Codes | Applicable product codes are listed in the attached. |
| Classification and Rule | Class IIb, as defined by Rule 4, laid down in Annex IX of the EC Medical Device Directive (93/42/EEC) |
| Conformity Assessment Route | Annex II |
| Notified Body Name, Identification number Address | The British Standards Institute (BSI) 2797 BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands |
| Authorised Representative in the European Community | Unomedical A/S, Aaholmvej 1-3, Osted, 43230, Lejre, Denmark |
| EC Certification Number | 00364 |
| GMDN Code and Term title | 43186 - Exudate-absorbent dressing, hydrophilic-gel |
| Harmonised Standards Applied: | EN ISO 13485:2016, EN ISO 10993:2009, EN ISO 14971:2012, EN1041:2008, EN 13726-1:2002, EN 13726-2:2002, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2009, ISO 15223-1:2016 |

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name:



Date: 11/May/2021

Gary Barrett, Vice President, Regulatory Affairs

{WTTF-007/ PR/DL20-050}

Trade/Brand Name: AQUACEL with Strengthening Fiber (WSF)

| Product Codes | Product Description |
|---------------|------------------------------------|
| 403770 | AQUACEL WSF 2X45CM STER (1X5PK) |
| 403772 | AQUACEL WSF 2.5X40CM STER (1X16PK) |
| 422624 | AQUACEL WSF 2.5X40CM STER (1X10PK) |
| 403774 | AQUACEL WSF 2X45CM STER(1X3PK) |
| 420127 | AQUACEL WSF 1X45CM STER(1X5PK) |