

## EC Declaration of Conformity

### Technical File WTTF-016

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): Foam Lite ConvaTec		
Product Codes	Applicable product codes are listed in the attached.		
Classification and Rule (Include Sterility / Measuring if applicable)	Class IIb, as defined in Article 1 and based on 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 <b>BSI Group The Netherlands B.V.</b> Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands		
Authorised Representative in the European Community	Unomedical A/S, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark		
(QA) Certification Number	CE 00364		
GMDN Code and Term title	44970 Exudate-absorbent dressing, non-gel		
Harmonised Standards Applied:	- BS EN ISO 13485: 2016 - BS EN ISO 14971: 2012 - ISO 10993-1: 2018 - ISO 10993-3: 2014 - ISO 10993-5: 2009 - ISO 10993-6: 2016 - ISO 10993-7:2008 - ISO 10993-10: 2010	- ISO 10993-11: 2017 - ISO 10993-17: 2009 - ISO 10993-18: 2020 - EN ISO 11135: 2014 - BS EN ISO 11607-1: 2020 - BS EN ISO 11607-2: 2020 - EN 1041: 2008 +A1: 2013 - EN ISO 15223-1: 2016	- BS EN 13726 -1: 2002 - BS EN 13726 -2: 2002 - BS EN 13726 -3: 2003 - BS EN 13726 -4: 2003 - BS EN 13726 -6: 2003 - BS EN 14644 -1: 2015

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name:

  
 Gary Barrett  
 Vice President, Regulatory Affairs

Date: 09/June 2021

**WTTF-016 Foam Lite**

Trade/Brand Name: Foam Lite

<b>REF Code</b>	<b>Description</b>	<b>Dressings / carton</b>	<b>Specifications</b>	<b>SAP</b>
421557	Foam Lite ConvaTec 8cm x 8cm	10 dressings per carton	PR20-299	1713678 (EUR) 1713679 (CEE)
421559	Foam Lite ConvaTec 10cm x 10cm	10 dressings per carton	PR20-299	1713684 (EUR) 1713685 (CEE)
421561	Foam Lite ConvaTec 15cm x 15cm	10 dressings per carton	PR20-299	1713691 (EUR) 1713692 (CEE)
421563	Foam Lite ConvaTec 5.5cm x 12cm	10 dressings per carton	PR20-299	1713697 (EUR) 1713698 (CEE)
421704	Foam Lite ConvaTec 15cm x 15cm	3 dressings per carton	PR20-299	1716709 (ES)
421707	Foam Lite ConvaTec 10cm x 10cm	3 dressings per carton	PR20-299	1716043 (ES)
421927	Foam Lite ConvaTec 5cm x 5cm	10 dressings per carton	PR20-299	1719849 (EUR) 1719850 (CEE)
421928	Foam Lite ConvaTec 10cm x 10cm	10 dressings per carton	PR20-299	1719852 (EUR) 1719853 (CEE)