

EC Declaration of Conformity

Technical Files WTTF-015 {P/TF14-008 AQUACEL Foam Adhesive Dressing}

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 Foam (Adhesive)		
Product Codes	Applicable product codes are listed in the attached.		
Classification and Rule (Include Sterility / Measuring if applicable)	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		
(QA/EC) Certification Number	CE 00364		
GMDN Code and Term title	43186- Exudate-absorbent dressing, hydrophilic-gel		
Harmonised Standards Applied:	ISO 13485: 2003 EN ISO 13485: 2012 EN ISO 14971: 2012 EN ISO 10993-1: 2009 EN ISO 10993-3:2014	EN ISO 10993-5: 2009 EN ISO 10993-7: 2008 EN ISO 10993-5: 2009 EN ISO 10993-11: 2009 EN ISO 15223-1: 2016	EN 1041: 2008 EN ISO 11135-1:2007 EN ISO 11135:2014 EN ISO 11607-1:2009 EN ISO 11607-2:2006

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: R. Sheridan

Date: 05 APR 2019

Rebecca Sheridan, Senior Director, AWC Franchise QARA

Trade/Brand Name: Foam Lite

ICC	Description
420680	AQUACEL® foam ADH 10X10 (1X10)
420619	AQUACEL® foam ADH 12.5X12.5(1X10)
420621	AQUACEL® foam ADH 17.5X17.5(1X10)
420623	AQUACEL® foam ADH 21X21(1X5)
420653	AQUACEL® foam ADH 21X21(1X10)
420624	AQUACEL® foam ADH 25X30(1X5)
420654	AQUACEL® foam ADH 25X30(1X10)
420625	AQUACEL® foam ADH HEEL 19.8X14 (1X5)
420655	AQUACEL® foam ADH HEEL 19.8X14 (1X10)
420626	AQUACEL® foam ADH SACRAL20X17(1X5)
420656	AQUACEL® foam ADH SACRAL20X17(1X10)
420804	AQUACEL® foam ADH 8X8(1X10)
420828	AQUACEL® foam ADHSACRAL Large (1X5)
421049	AQUACEL® foam ADH SACRAL Large (1X10)
421149	AQUACEL® foam ADH 8X13 (1X10)
421150	AQUACEL® foam ADH 10X20 (1X5)
421151	AQUACEL® foam ADH 10X20 (1X10)
421152	AQUACEL® foam ADH 10X25 (1X5)
421153	AQUACEL® foam ADH 10X25 (1X10)
421154	AQUACEL® foam ADH 10X30 (1X5)
421155	AQUACEL® foam ADH 10X30 (1X10)
420618	AQUACEL® foam ADH 12.5X12.5(1X3)
421452	AQUACEL® foam ADH SACRAL 20x17(1X3) ES
421451	AQUACEL® foam ADH HEEL 19.8x14(1X3) ES
421494	AQUACEL® foam ADH 17.5x17.5 (1X3) ES
420620	AQUACEL® foam ADH 12.5X12.5(1X16)
420808	AQUACEL® foam ADH 8X8(1X16)