

EC Declaration of Conformity
In relation to Aquacel Foam Adhesive Dressing
Technical File ICKTF-079 (TP/TF14-008)

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

ConvaTec Limited / The Manufacturer 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 Dressing
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) 0086 Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom
EC Certification Number	CE 00364
Certificate commencement Date & Expiry	Commencement 09 December 1994 Expiry 20 October 2018
GMDN Code and Term title	43186, Exudate-absorbent dressing, hydrophilic-gel
Harmonized Standards Applied	EN ISO 13485:2012, EN ISO 10993:2003/9, EN ISO 14971:2012, EN1041: 2008, EN13726, EN ISO 11135-1:2007, EN ISO 11135: 2014, EN ISO 11607-1:2009, ISO 15223-1:2012, EN1041:2008 & A1:2013

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name:



Duncan Rowley
Director, RAQA EMEA

Date:

04 Aug 2017

Issue: 15

Date: 04/Aug/2017

ConvaTec Limited Registered No. 1309639

Registered Office: ConvaTec Limited, GDC First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU

Tel +44(0) 1244 584300 Fax: +44 (0) 1244 584311 www.convatec.com

AQUACEL Foam Adhesive Dressing (TP/TF14-008)

Trade/Brand Name:

Product Codes	Product Description
420618	12.5x12.5
420619	12.5x12.5
420620	12.5x12.5
420621	17.5x17.5
420623	21x21
420624	25x30
420625	19.8x14
420626	20x17
420653	21x21
420654	25x30
420655	19.8x14
420656	20x17
420680	10x10
420804	8x8
420808	8x8
420828	Sacral Large
421049	Sacral Large
421149	8x13
421150	10x20
421151	10x20
421152	10x25
421153	10x25
421154	10x30
421155	10x30
421451	19.8x14
421452	20x17
421494	17.5x17.5

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