ConvaTec

EC Declaration of Conformity

Design Dossier DD002 {TP/TF14-011}

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 Ag Foam non-Adhesive Dressing
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule (Include Sterility / Measuring if applicable)	Class III, as defined by Rule 13, laid down in Annex IX of the EC Medical Device Directive (93/42/EEC)
Conformity Assessment Route	Annex II, including section 4
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	ISO 13485:2016 & EN ISO 13485:2016 Certificate Number MD 670405 EC Design-Examination Certificate No. CE 544321
GMDN Code and Term title	47474, Exudate-absorbent dressing, hydrophilic-gel, antimicrobial, sterile
Harmonised Standards Applied:	Attached

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

R. Sheridan 10 DEC 2019

Name: Rebecca Sheridan
Senior Director, Advanced Wound Care QARAC

Date: 06/DEC/2019

Issue: 7
Date: 06/DEC/2019

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 Ag Foam Adhesive Dressing- DD002 {TP/TF14-011}

Harmonised Standards Used:

EN ISO 13485:2012 & 2016
ISO 13485: 2003, 2012 & 2016
EN ISO 10993-1:2003, 2009
EN ISO 10993-3:2014
EN ISO 10993-5:2009
EN ISO 10993-7:2008
EN ISO 10993-11:2009
EN ISO 30993-1:1994
EN ISO 14971: 2012, 2007, 2009
EN ISO 11137:2006
EN ISO 11135-1:2007 & 2014
EN 540
EN ISO 14155-1:2003 & 2011
EN 1041:2008 +A1: 2013
EN 980:2008
EN ISO 15223-1:2012, 2016
EN 13726-1:2002
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN 22442-1:2007
EN ISO 11737-1:2006
BS EN 13726-1:2002
BS EN 13726-2:2002
BS EN 13726-3:2002
BS EN 13726-4:2002
BS EN 13726-6:2002
MEDDEV 2.7.1 Rev.3

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AQUACEL Ag Foam Non-Adhesive Dressing- DD002 {TP/TF14-011}

Trade/Brand Name:

Product Codes	Product Description, Dressing size & Pack quantity
420638	AQUACEL Ag Foam Non-Adhesive, 5cmx5cm, 3/pack
420639	AQUACEL Ag Foam Non-Adhesive, 5cmx5cm, 10/pack
420640	AQUACEL Ag Foam Non-Adhesive, 5cmx5cm, 16/pack
420641	AQUACEL Ag Foam Non-Adhesive, 10cmx10cm, 3/pack
420642	AQUACEL Ag Foam Non-Adhesive, 10cmx10cm, 10/pack
420643	AQUACEL Ag Foam Non-Adhesive, 10cmx10cm, 16/pack
420187	AQUACEL Ag Foam Non-Adhesive, 12.5cmx12.5cm, 16/pack
420644	AQUACEL Ag Foam Non-Adhesive, 15cmx15cm, 3/pack
420645	AQUACEL Ag Foam Non-Adhesive, 15cmx15cm, 5/pack
420664	AQUACEL Ag Foam Non-Adhesive, 15cmx15cm, 10/pack
420189	AQUACEL Ag Foam Non-Adhesive, 17.5cmx17.5cm, 10/pack
420646	AQUACEL Ag Foam Non-Adhesive, 20cmx20cm, 5/pack
420665	AQUACEL Ag Foam Non-Adhesive, 20cmx20cm, 10/pack
420806	AQUACEL Ag Foam Non-Adhesive, 15cmx20cm, 5/pack
420810	AQUACEL Ag Foam Non-Adhesive, 15cmx20cm, 10/pack
420189	AQUACEL Ag Foam Non-Adhesive, 17.5cmx17.5cm, 10/pack
420646	AQUACEL Ag Foam Non-Adhesive, 20cmx20cm, 5/pack
420665	AQUACEL Ag Foam Non-Adhesive, 20cmx20cm, 10/pack

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