

EC Declaration of Conformity

Technical File WTTF-015 {PR/DL20-297-AQUACEL Foam Non-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 products conform 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 (Non-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, 4320, Lejre, Denmark
(QA/EC) Certification Number	ISO 13485:2016 & EN ISO 13485:2016 Certificate Number MD 670405 CE 00364
GMDN Code and Term title	43186, Exudate-absorbent dressing, hydrophilic-gel, sterile
Harmonised Standards Applied:	Attached

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited



Name: Gary Barrett
 Vice President Regulatory Affairs

Date: 25th May 2021

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Harmonised Standards Used:

EN ISO 13485:2016 and ISO 13485:2016

EN ISO 10993-1:2009

EN ISO 10993-3:2014

EN ISO 10993-5:2009

EN ISO 10993-7:2008

EN ISO 10993-11:2018

EN ISO 14971: 2012

EN ISO 11135-1:2007

EN 1041:2008

EN ISO 15223-1:2016

EN 13726-1:2002

EN ISO 11607-1:2009

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Trade/Brand Name:

Product Codes	SAP	Product Description, Dressing size & Pack quantity
420186	1705594	AQUACEL Foam N/ADH 12.5cmX12.5cm, 1X16 FR
422625	1729904	AQUACEL FOAM N/ADH 12.5 X 12.5 CM 1X 10 FR
420188	1705596	AQUACEL Foam N/ADH 17.5cmX17.5cm, 1X10 FR
420631	1703984	AQUACEL Foam N/ADH 5cmX5cm, 1X10 EUR
420631	1703986	AQUACEL Foam N/ADH 5cmX5cm, 1X10 CEE
420633	1703989	AQUACEL Foam N/ADH 10cmX10cm, 1X10 EUR
420633	1703991	AQUACEL Foam N/ADH 10cmX10cm, 1X10 CEE
420633	1730135	AQUACEL Foam N/ADH 10cmX10cm, 1X10 DE
413623	1710606	AQUACEL Foam N/ADH 10cmX20ccm, 1X10 CEE
421156	1710671	AQUACEL Foam N/ADH 10cmX20cm, 15 EUR
421156	1710672	AQUACEL FOAM N/ADH 10X20CM (1X5) CEE
420635	1703995	AQUACEL Foam N/ADH 15cmX15cm, 1X5 EUR
420635	1703997	AQUACEL Foam N/ADH 15cmX15cm, 1X5 CEE
420652	1704131	AQUACEL Foam N/ADH 15cmX15cm, 1X3 ES
420637	1704003	AQUACEL Foam N/ADH 15cmX20cm, 1X5 EUR
420637	1704005	AQUACEL Foam N/ADH 15cmX20ccm, 1X5 CEE
420663	1704199	AQUACEL Foam N/ADH 15cmX20cm, 1X10 EUR
420636	1703999	AQUACEL Foam N/ADH 20cmX20cm, 1X5 EUR
420636	1704001	AQUACEL Foam N/ADH 20cmX20cm, 1X5 CEE
420662	1704198	AQUACEL Foam N/ADH 20cmx20cm, 1X10 EUR