EC Declaration of Conformity

Technical File {WTSTF-006, PR/DL20-286}

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 EXTRA
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule	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
EC Certification Number	00364
GMDN Code and Term title	43186 - Exudate-absorbent dressing, hydrophilic-gel
Harmonised Standards Applied:	EN ISO 13485:2016, EN ISO 10993:2009, EN ISO 14971:2012, EN1041: 2008, EN 13726-1:2002, EN 13726-2:2002, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2009, ISO 15223-1:2016

Issued in Deeside, UK.
Signed for and on behalf of ConvaTec Limited

Name:

Gary Barrett, Vice President, Regulatory Affairs (06/May/2021)

Issue: 11
Date: 06/May/2021

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

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Trade/Brand Name: AQUACEL EXTRA

Product Codes	Product Description
420671	5 x 5 cm
420816	5 x 5 cm
420672	10 x 10 cm
420814	10 x 10 cm
420815	10 x 10 cm
420674	10 x 12 cm
420823	12.5 x 12.5 cm
422627	12.5 x 12.5 cm
420819	13.5 x 15 cm
422626	13.5 x 15 cm
420826	15 x 13.5 cm
420673	15 x 15 cm
420817	15 x 15 cm
420820	4 x 10 cm
420818	5 x 10 cm
420825	5 x 10 cm
420821	4 x 20 cm
420822	4 x 30 cm
420824	18 x 23 cm
422622	20 x 24 cm
423409	20 x 24 cm

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History Page

Issue number	Date	Comment
1	22 Aug 2011	First Issue
2	5 Apr 2013	Additional sizes/New codes
3	19 Apr 2013	420874 corrected to 420674
4	7 June 2013	Additional sizes/new codes
5	26 Nov 2013	Update to address BSI NC's from Sept 2012 TF audit
6	13 Oct 2017	New DOC format, update for Re-brand and PMK packaging change
7	25 Oct 2017	Update to remove expiry date of CE00364 cert
8	19 Mar 2019	Update to Notified Body, addition of EC rep
9	25 Jun 2020	Update to harmonized standards
10	08 Feb 2021	Additional sizes/new codes
11	05 May 2021	Additional size/new code

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