

EC Declaration of Conformity

Technical File WTTF-015 {PR/DL20-296-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 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 (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

Date: 25th May 2021

Vice President Regulatory Affairs

AQUACEL Foam Adhesive Dressing- {PR/DL20-296}

Harmonised Standards Used:

EN 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 14971: 2012
EN ISO 11135-1:2007
EN 1041:2008
EN ISO 15223-1:2016
EN 13726-1:2002
EN ISO 11607-1:2009

AQUACEL Foam Adhesive Dressing- {PR/DL20-296}

Trade/Brand Name: AQUACEL Foam (Adhesive)

Product Codes	SAP	Product Description, Dressing size & Pack quantity
420804	1707743	AQUACEL ADH Foam 8cm x 8cm, 1X10 EUR
420804	1730134	AQUACEL ADH Foam 8cm x 8cm, 1X10 DE
420618	1703934	AQUACEL ADH Foam 12.5cm X 12.5cm, 1X3 ES
420619	1703935	AQUACEL ADH Foam 12.5cm x 12.5cm, 1X10 EUR
420619	1703937	AQUACEL ADH Foam 12.5cm x 12.5cm, 1X10 CEE
420620	1703939	AQUACEL ADH Foam 12.5cm x 12.5cm, 1X16 FR
420621	1703940	AQUACEL ADH Foam 17.5cm x 17.5cm 1X10 EUR
420621	1703942	AQUACEL ADH Foam 17.5cm x 17.5cm, 1X10 CEE
422350	1723885	AQUACEL ADH Foam 15cm X 15cm, 1X10 EUR
422350	1723887	AQUACEL ADH Foam 15cm X 15cm, 1X10 CEE
420680	1705400	AQUACEL ADH Foam 10cm X 10cm, 1X10 EUR
420680	1730133	AQUACEL ADH Foam 10cm X 10cm, 1X10 DE
420680	1705401	AQUACEL ADH Foam 10cm X 10cm, 1X10 CEE
421149	1710650	AQUACEL ADH Foam 8cm X 13cm, 1X10 EUR
421149	1710651	AQUACEL ADH Foam 8cm X 13cm, 1X10 CEE
420655	1704191	AQUACEL ADH Foam Heel, 1X10 EUR
420625	1703953	AQUACEL ADH Foam Heel,19.8cmX14cm, 1X5 EUR
420625	1703955	AQUACEL ADH Foam Heel,19.8cmX14cm, 1X5 CEE
421451	1713243	AQUACEL ADH Foam Heel, 1X3 ES
421049	1710043	AQUACEL Foam ADH SACRAL LRG 1X10 EUR
420828	1710041	AQUACEL Foam ADH SACRAL LRG 1X5 EUR
420656	1704192	AQUACEL Foam ADH SACRAL 1X10 EUR
420626	1703957	AQUACEL Foam ADH SACRAL 20cmX16.9cm, 1X5 EUR
421452	1713241	AQUACEL Foam ADH SACRAL 1X3 ES
420626	1703959	AQUACEL Foam ADH SACRAL 20cmX16.9cm, 1X5 CEE
420653	1704189	AQUACEL Foam ADH 21cmX21cm, 1X10 EUR
420623	1703945	AQUACEL Foam ADH 21cmX21cm, 1X5 EUR
420623	1703947	AQUACEL Foam ADH 21cmX21cm, 1X5 CEE
420624	1703951	AQUACEL Foam ADH 25cmX30cm, 1X5 CEE
420624	1703949	AQUACEL Foam ADH 25cmX30cm, 1X5 EUR
421150	1710653	AQUACEL Foam ADH 10cmX20cm, 1X5 EUR
421151	1710656	AQUACEL Foam ADH 10cmX20cm, 1X10 EUR
421151	1710657	AQUACEL Foam ADH 10cmXX20cm, 1X10 CEE
421152	1710659	AQUACEL Foam ADH 10cmX25cm, 1X5 EUR

Product Codes	SAP	Product Description, Dressing size & Pack quantity
421153	1710662	AQUACEL Foam ADH10cmX25cm, 1X10 EUR
421153	1710663	AQUACEL Foam ADH 10cmX25cm, 1X10 CEE
421154	1710665	AQUACEL Foam ADH 10cmX30cm, 15 EUR
421155	1710668	AQUACEL Foam ADH 10cmX30cm, 1X10 EUR
421155	1710669	AQUACEL Foam ADH 10cmX30cm, 1X10 CEE
421494	1713244	AQUACEL Foam ADH 17.5cmX17.5cm, 1X3 ES