

EC Declaration of Conformity

Design Dossier DD002 (PR20-292)

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

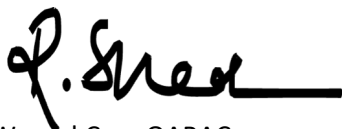
This Declaration is made under the sole responsibility of the manufacturer, ConvaTec Limited, who herewith declares that the attached list of mentioned product conforms to the applicable essential requirements and provisions of Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC) concerning medical devices.

Product Name	Trade/ Brand Name(s): AQUACEL Ag+ Ribbon with Strengthening Fibre
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 66524
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

Name: Rebecca Sheridan



Date: 21/JUL/2020

Senior Director, Advanced Wound Care QARAC

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Harmonised Standards Used:

EN ISO 13485:2012 & 2016
ISO 13485: 2012 & 2016
EN ISO 10993-1:2003, 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
EN 980:2008
EN ISO 1522301:2012
EN 13726-1:2002
EN ISO 11607-1:2009
EN ISO 11607-2:2006
EN 22442-1:2007
EN ISO 11737-1:2006

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Trade/Brand Name:

Product Codes	Product Description, Dressing size & Pack quantity
413570	AQUACEL Ag+ Ribbon Dressing with Silver and Strengthening Fibre, 1cm X 45cm; 5/pack
413571	AQUACEL Ag+ Ribbon Dressing with Silver and Strengthening Fibre, 2cm X 45cm; 5/pack
413575	AQUACEL Ag+ Ribbon Dressing with Silver and Strengthening Fibre, 2.5cm X 40cm; 16/pack
413572	AQUACEL Ag+ Ribbon Dressing with Silver and Strengthening Fibre, 2.5cm X 45cm; 3/pack

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History Page

Issue No	Date	Comment
1	20/DEC/2013	First Issue based on update to EC Design Examination Certificate CE66524
2	29/NOV/2016	DoC updated to reflect new supplement dossier for BSI submission for the following change; Aquacel Ag+ Tow scale up
3	08/FEB/2018	Certificate Renewal
4	12/APR/2018	Update to Antistat in Lyocell TOW
5	14/MAR/2019	Change of Notified Body from BSI UK to BSI Netherlands
6	12/SEP/2019	DoC updated to reflect the certificate following BSI review of Supplement 42: New Ag Annex in Rhymney, Fluid handling sampling plans & BEC alignment in unit 1
7	21/JUL/2020	Change in pallet size for sterilization at Synergy Health Sterilisation UK Ltd (Bradford) for Aquacel Ag+ Ribbon.