EC Declaration of Conformity

Technical File WTTF-004 {PR/DL20-038 CarboFlex® Odour Control Dressing}

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

ConvaTec Limited 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): **CarboFlex®**
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 and Annex VII
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
(CE) Certification Number	CE 00364
GMDN Code and Term title	44897- Odour Absorbing Dressing
Harmonised Standards Applied:	EN ISO 13485: 2016
	EN ISO 14971: 2012
	EN ISO 10993-1: 2009
	EN ISO 10993-5: 2009
	EN ISO 10993-10: 2010
	EN ISO 15223-1: 2016
	EN 1041: 2008
	EN ISO 11137-1:2015
	EN ISO 11137-2:2015
	EN 13726-1:2002
	EN 13726-2:2002

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

Name: R. Sheridan Date: 23 Nov 2020

Rebecca Sheridan
Senior Director, AWC Franchise QARAC

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

Trade/Brand Name: **CarboFlex™ Odour Control Dressing**

Product Codes	
403202	403314
403203	403315
403204	

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History Page

Issue number	Date	Comment
1	17 NOV 1997	Original Issue
2	22 OCT2002	New format to certificate. Amendment to product name to match specification (PR20-038)
3	13 NOV 2003	Change of signatory to conform with SOP 706
4	28 SEP 2004	Simplification to template to remove quality systems
5	1 AUG 2008	New letter headed paper
6	30 APR 2010	Technical File updated inline with change in manufacturing process
7	16 MAY 2011	New raw material for Alginate. Supplementary insert added considering evevated Mn levels.
8	16 NOV 2011	Previous Declaration of Confomirty showed incorrect specficiation name
9	10 FEB 2012	New alginate raw material supplier
10	26 NOV 2013	Update to address BSI audit observations and non-conformities from September 2012 Technical File audit
11	26 NOV 2015	Update to DoC following update to Essential requirements checklist and technical file to address audit actions
12	27 FEB 2018	Update to ERC due to new Clincal Evalaution Report
13	20 MAR 2019	Change of Notified Body from BSI UK to BSI Netherlands
14	30 SEPT 2019	Update made to file to include new supporting documentation including design verification and validation, artwork and Clinical Evaluation Report.
15	22 JUL 2020	Change in spin finish in pad payer material
16	23 NOV 2020	Update tp section 7.4 technical file and ERC for EN ISO 11607-1 and EN 11607-2

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