

	Effective Date:	25-Nov-2024		
	Status:	Effective	Version:	5.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	Title:	Declaration of Conformity Form		

EU Declaration of Conformity

Carboflex

Technical Documentation MDR-AWCTF 001

Issued by: ConvaTec

We hereby declare;

- that the listed product/s comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745 and any other applicable European Union legislation
- that this EU declaration of conformity is issued under the sole responsibility of ConvaTec.

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

Singel Reg # (SRN): GB-MF-000001770

Authorized Representative: Unomedical a/s, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark

Product Name: Carboflex Odour Control Dressing

Basic UDI-DI: 768455AWC00083N

GMDN Code & Name: 44897 - Odour Absorbing Dressing

EMDN Code & M04040902 - Activated Charcoal Dressings, combined with other substances

Description: CarboFlex Odour Control Dressing is intended for the management of malodorous wounds. It may be used as a primary or secondary dressing as per the indications for use.

Intended Purpose:

Device(s) & Cat. #: Refer to Appendix A

Risk Class: Class IIb as per Rule 4 (The Medical Devices Regulations 2002 (S) 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478))

Notified Body: Notified Body Number 2797
BSI Group The Netherlands B.V.
Say Building
John.M. Keynesplein 9
1066 EP Amsterdam

Certificate(s): EU Quality Management System Certificate (Regulation (EU) 2017/745, Annex IX Chapter I and III)
MDR#: 738968, Issued by BSI

Signed by:

 Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Jan 27, 2026 | 12:16:35 PM GMT
79126EF62CD04B7AA0479B4D5AA7AE98

Legal Manufacturer authorized signature:

Signature: _____

Date: Jan 27, 2026

Name: Steeve Lamvohee

Title: Head of IC/AWC Regulatory Affairs

Place of Issue: *Deeside, Flintshire*

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Appendix A: Products

ICC	SAP	Description	UDI-DI
403202	1052952	CarboFlex Dressing 10cm x 10cm (1X10PK)	00768455059102
	1226550		00768455110995
403203	1226571	CarboFlex Dressing 8cm x 15cm (1X5PK)	00768455111008
403204	1226671	CarboFlex Dressing 15cm x 20cm (1X5PK)	00768455111015