	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 & Description:** M04040902 - Activated Charcoal Dressings, combined with other substances



**Intended Purpose:** 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.

**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*

 <b>convatec</b> – forever caring –	Effective Date:	25-Nov-2024		
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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