

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

EU Declaration of Conformity
Kaltostat Dressings – Sterile
(Technical Documentation MDR AWCTF 015)

Issued by: ConvaTec Limited

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

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

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

Single Reg # (SRN): DK-AR-000000941

Product Name: Kaltostat Dressings

Basic UDI-DI: 768455AWC00053G

GMDN Code & Name: 43186- Exudate- absorbent dressing, hydrophilic-gel, non-antimicrobial

EMDN Code & Description: M040402 - Alginate Dressings

Intended Purpose: Kaltostat dressings may be used, with consultation of a healthcare professional, for the management of moderate to heavily exuding wounds. Kaltostat dressings are designed to absorb exudate and protect the wound from contamination. Kaltostat rope dressing is designed to be used to manage cavity wounds.

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

Risk Class: Class IIb as per Rule 4 (MDR Annex VIII)

Notified Body: BSI 2797

Certificate(s): EU Quality Management System Certificate (Regulation (EU) 2017/745, Annex IX Chapter I and III) MD 738968
MDR #: 738968 R000, Issued by BSI (2021-11-10)

Signed by:

 Signer Name: Steeve Lamvohee
 Signing Reason: I approve this document
 Signing Time: Nov 27, 2025 | 8:15:17 PM GMT
 79126EF62CD04B7AA0479B4D5AA7AE98

Legal Manufacturer authorized signature:

Signature: _____ **Date:** Nov 27, 2025
Steeve Lamvohee
Head of IC/AWC Regulatory Affairs
 Place of Issue: *Deeside, Flintshire*

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Appendix A: Products

ICC	SAP	Product Description	UDI-DI
168101	1226549	KALTOSTAT DRS WT 10X10CM 1X5PK STER EUR	00768455039234
168117	1052785	KALTOSTAT CAVITY DRS 2G 1X5 STER EEU	00768455054411
	1213285	KALTOSTAT ROPE 2GM WT 1X5PK STER EUR	00768455111022
168210	1052786	KALTOSTAT DRS 5X5CM 1X10 STER EEU	00768455054398
	1203783	KALTOSTAT DRS WT 5X5CM 1X10PK STER EUR	00768455111039
168212	1052787	KALTOSTAT DRS 7.5X12CM 1X10 STER EEU	00768455054367
	1226681	KALTOSTAT DRS WT 7.5X12CM 1X10PK STER EUR	00768455111046
168214	1052788	KALTOSTAT DRS 10X20CM 1X10 STER EEU	00768455054374
	1226579	KALTOSTAT DRS WT 10X20CM 1X10PK STER EUR	00768455111053
168215	1052789	KALTOSTAT DRS 15X25CM 1X10 STER EEU	00768455054381
	1226630	KALTOSTAT DRS WT 15X25CM 1X10PK STER EUR	00768455111060
168219	1226636	KALTOSTAT DRS WT 30X60CM 1X5PK STER EUR	00768455111077