

	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

ConvaFoam Non-Adhesive, ConvaFoam Border and ConvaFoam Silicone Dressings – Sterile

Technical Documentation MDR AWCTF 033

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

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

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

Product Name: 43186 Exudate-absorbent dressing, hydrophilic-gel

Basic UDI-DI: ConvaFoam Non-Adhesive - 768455AWC00353R
ConvaFoam Border - 768455AWC00343P
ConvaFoam Silicone- 768455AWC00333M

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

EMDN Code & Description: M040405 Dressings, Hydrogel – ConvaFoam Non-Adhesive & ConvaFoam Border
M040407 Dressings, Silicone – ConvaFoam Silicone

Intended Purpose:

ConvaFoam Non-Adhesive, Border and Silicone Dressings: ConvaFoam dressings may be used, with the consultation of a healthcare professional, for the management of exuding and non-exuding wounds, and for the protection of intact skin.

ConvaFoam dressings may also be used on intact skin as part of a pressure injury prevention protocol.

ConvaFoam dressings may be used as a primary or secondary dressing.

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

Risk Class: Class IIb MDR Annex VIII

Common Specifications

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(CS):

Notified Body: BSI 2797

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

**Legal Manufacturer
authorized
signature:**

Signed by:
Steve Lamvohee
 Signer Name: Steeve Lamvohee
 Signing Reason: I approve this document
 Signing Time: Dec 19, 2024 | 1:58:51 PM GMT
 79126EF62CD04B7AA0479B4D5AA7AE98

Signature: _____ **Date:** Dec 19, 2024
Steeve Lamvohee

Head of IC/AWC Regulatory Affairs

Place of Issue: Deeside, Flintshire

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Appendix A: Products

ConvaFoam Non-Adhesive

ICC	SAP	Description
423355	1733678	CONVAFOAM N/ADH 10X10CM 1X10 EUR
423357	1733683	CONVAFOAM N/ADH 15X15CM 1X5 EUR
423355	1733681	CONVAFOAM N/ADH 10X10CM 1X10 DE
423357	1747005	CONVAFOAM N/ADH 15X15CM 1X5 DE
423358	1733686	CONVAFOAM N/ADH 15X15CM 1X3 ES
423354	1733675	CONVAFOAM N/ADH 5X5CM 1X10 EUR
423354	1747006	CONVAFOAM N/ADH 5X5CM 1X10 DE
423356	1746156	CONVAFOAM N/ADH 12.5X12.5CM (1X10PK)EUR
423359	1746157	CONVAFOAM N/ADH 17.5X17.5CM (1X10PK)EUR
423360	1733756	CONVAFOAM N/ADH 20X20CM 1X5 EUR
423360	1747022	CONVAFOAM N/ADH 20X20CM 1X5 DE
423361	1746155	CONVAFOAM N/ADH 10X20CM (1X10PK) EUR
423362	1733692	CONVAFOAM N/ADH 10X20CM 1X5 EUR
423362	1747021	CONVAFOAM N/ADH 10X20CM 1X5 DE
423363	1733688	CONVAFOAM N/ADH 15X20CM 1X5 EUR
423363	1747020	CONVAFOAM N/ADH 15X20CM 1X5 DE
423364	1733691	CONVAFOAM N/ADH 15X20CM 1X10 EUR
423379	1733694	CONVAFOAM N/ADH 20X20CM 1X10 EUR

ConvaFoam Silicone

ICC	SAP	Description
423252	1732209	CONVAFOAM SILICONE 8X8CM 1X10 EUR
423253	1732211	CONVAFOAM SILICONE 10X10CM 1X10 EUR
423525	1735582	CONVAFOAM SILICONE 12.5X12.5CM 1X10 EUR
423254	1732213	CONVAFOAM SILICONE 15X15CM 1X10 EUR
423527	1735587	CONVAFOAM SILICONE 17.5X17.5CM 1X10 EUR
423530	1735595	CONVAFOAM SILICONE MULTISITE 1X5 EUR
423256	1732217	CONVAFOAM SILICONE LG SACRAL 1X5 EUR
423257	1732219	CONVAFOAM SILICONE SM SACRAL 1X5 EUR
423536	1735603	CONVAFOAM SILICONE 21X21CM 1X5 EUR
423535	1735602	CONVAFOAM SILICONE 21X21CM 1X10 EUR
423255	1732215	CONVAFOAM SILICONE MULTISITE 1X10 EUR
423252	1747002	CONVAFOAM SILICONE 8X8CM 1X10 DE
423253	1735581	CONVAFOAM SILICONE 10X10CM 1X10 DE
423908	1747003	CONVAFOAM SILICONE 15X15CM 1X5 DE
423530	1747007	CONVAFOAM SILICONE MULTISITE 1X5 DE
423256	1747009	CONVAFOAM SILICONE LG SACRAL 24CMX21.5CM 1X5 DE
423257	1747010	CONVAFOAM SILICONE SM SACRAL 20CMX16.9CM 1X5 DE
423856	1746159	CONVAFOAM SILICONE 10X10CM (1X3PK) ES

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423857	1746160	CONVAFOAM SILICONE 15X15CM (1X3PK) ES
423858	1746161	CONVAFOAM SILICONE LG SACRAL (1X3PK) ES
423531	1735597	CONVAFOAM SILICONE MULTISITE 1X3 ES

ConvaFoam Border

ICC	SAP	Description
423258	1732140	CONVAFOAM BORDER 8X8CM 1X10 EUR
423259	1732143	CONVAFOAM BORDER 10X10CM 1X10 EUR
423260	1732147	CONVAFOAM BORDER 12.5X12.5CM 1X10 EUR
423262	1732151	CONVAFOAM BORDER 15X15CM 1X10 EUR
423263	1732154	CONVAFOAM BORDER 17.5X17.5CM 1X10 EUR
423267	1732163	CONVAFOAM BORDER MULTISITE 1X5 EUR
423266	1732161	CONVAFOAM BORDER MULTISITE 1X10 EUR
423270	1732167	CONVAFOAM BORDER LARGE SACRAL 1X5 EUR
423269	1732166	CONVAFOAM BORDER LARGE SACRAL 1X10 EUR
423272	1732170	CONVAFOAM BORDER SMALL SACRAL 1X5 EUR
423271	1732169	CONVAFOAM BORDER SMALL SACRAL 1X10 EUR
423275	1732175	CONVAFOAM BORDER 21X21CM 1X5 EUR
423274	1732174	CONVAFOAM BORDER 21X21CM 1X10 EUR
423258	1732142	CONVAFOAM BORDER 8X8CM 1X10 DE
423259	1732146	CONVAFOAM BORDER 10X10CM 1X10 DE
423260	1747004	CONVAFOAM BORDER 12.5X12.5CM 1X10 DE
423916	1747011	CONVAFOAM BORDER 17.5X17.5CM 1X5 DE
423267	1747008	CONVAFOAM BORDER MULTISITE 1X5 DE
423270	1747012	CONVAFOAM BORDER LARGE SACRAL 24CMX21.5CM 1X5 DE
423272	1747013	CONVAFOAM BORDER SMALL SACRAL 20CMX16.9CM 1X5 DE
423275	1747014	CONVAFOAM BORDER 21X21CM 1X5 DE
423261	1732150	CONVAFOAM BORDER 12.5X12.5CM 1X3 ES
423264	1732157	CONVAFOAM BORDER 17.5X17.5 1X3 ES
423268	1732165	CONVAFOAM BORDER MULTISITE 1X3 ES
423273	1732173	CONVAFOAM BORDER SMALL SACRAL 1X3 ES

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Change History

Revision number	Date	Change	Author																																										
1.0	17 Jul 2024	Initial issue of UKCA under The Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).	Rebecca Davies																																										
2.0	Dec 19, 2024	Line extension to include the following sizes: <table><thead><tr><th>ICC</th><th>SAP</th><th>DESCRIPTION</th></tr></thead><tbody><tr><td>423354</td><td>1733675</td><td>CONVAFOAM N/ADH 5X5CM 1X10 EUR</td></tr><tr><td>423354</td><td>1747006</td><td>CONVAFOAM N/ADH 5X5CM 1X10 DE</td></tr><tr><td>423356</td><td>1746156</td><td>CONVAFOAM N/ADH 12.5X12.5CM (1X10PK)EUR</td></tr><tr><td>423359</td><td>1746157</td><td>CONVAFOAM N/ADH 17.5X17.5CM (1X10PK)EUR</td></tr><tr><td>423360</td><td>1733756</td><td>CONVAFOAM N/ADH 20X20CM 1X5 EUR</td></tr><tr><td>423360</td><td>1747022</td><td>CONVAFOAM N/ADH 20X20CM 1X5 DE</td></tr><tr><td>423361</td><td>1746155</td><td>CONVAFOAM N/ADH 10X20CM (1X10PK) EUR</td></tr><tr><td>423362</td><td>1733692</td><td>CONVAFOAM N/ADH 10X20CM 1X5 EUR</td></tr><tr><td>423362</td><td>1747021</td><td>CONVAFOAM N/ADH 10X20CM 1X5 DE</td></tr><tr><td>423363</td><td>1733688</td><td>CONVAFOAM N/ADH 15X20CM 1X5 EUR</td></tr><tr><td>423363</td><td>1747020</td><td>CONVAFOAM N/ADH 15X20CM 1X5 DE</td></tr><tr><td>423364</td><td>1733691</td><td>CONVAFOAM N/ADH 15X20CM 1X10 EUR</td></tr><tr><td>423379</td><td>1733694</td><td>CONVAFOAM N/ADH 20X20CM 1X10 EUR</td></tr></tbody></table> Updates made to the following technical file sections: Section 3.3 Market History Section 4 Device Labelling Section 5.2.4 In-process Inspections Section 8.6.1 Sterilisation Controls Section 8.7.2 Packaging Validation Section 9.3 Post Market Surveillance	ICC	SAP	DESCRIPTION	423354	1733675	CONVAFOAM N/ADH 5X5CM 1X10 EUR	423354	1747006	CONVAFOAM N/ADH 5X5CM 1X10 DE	423356	1746156	CONVAFOAM N/ADH 12.5X12.5CM (1X10PK)EUR	423359	1746157	CONVAFOAM N/ADH 17.5X17.5CM (1X10PK)EUR	423360	1733756	CONVAFOAM N/ADH 20X20CM 1X5 EUR	423360	1747022	CONVAFOAM N/ADH 20X20CM 1X5 DE	423361	1746155	CONVAFOAM N/ADH 10X20CM (1X10PK) EUR	423362	1733692	CONVAFOAM N/ADH 10X20CM 1X5 EUR	423362	1747021	CONVAFOAM N/ADH 10X20CM 1X5 DE	423363	1733688	CONVAFOAM N/ADH 15X20CM 1X5 EUR	423363	1747020	CONVAFOAM N/ADH 15X20CM 1X5 DE	423364	1733691	CONVAFOAM N/ADH 15X20CM 1X10 EUR	423379	1733694	CONVAFOAM N/ADH 20X20CM 1X10 EUR	Sadie Norcross
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