	Effective Date:	29-Aug-2023		
	Status:	Effective	Version:	3.0, CURRENT
	Group:	Change Control	Sites:	CC-Deeside-R&D
	Artifact Name:	Form	Name:	FORM-014357
	Title:	WI-0506 Declaration of Conformity Form		

EU Declaration of Conformity

[Aquacel Foam Adhesive and Non Adhesive] – [Sterile]

(Technical Documentation MDR [AWC/TF [05]])

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: *[Aquacel Foam Adhesive and Non Adhesive Dressings]*

Basic UDI-DI: *[768455AWC00063J]*

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

EMDN Code & Description: *[M040405-DRESSINGS, HYDROGEL]*


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

Risk Class: *[Class IIb (MDR Annex VIII)]*

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)]

 convatec <small>— forever caring —</small>	Effective Date:	29-Aug-2023		
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DocuSigned by:




Signer Name: Steeve Lamvohee
 Signing Reason: I approve this document
 Signing Time: Mar 3, 2024 | 8:22:53 AM GMT
 79126EF62CD04B7AA0479B4D5AA7AE98


Date: Mar 3, 2024

**Legal Manufacturer
 authorized
 signature:**

[Steeve Lamvohee]


[Head of RA IC/AWC]

Place of Issue: *[Deeside, Flintshire]*

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Appendix A: Products

ICC	SAP	Description
420618	1703934	AQUACEL ADH Foam 12.5 x 12.5 cm 1x3 ES
420619	1703935	AQUACEL ADH Foam 12.5 x 12.5 cm 1x10 EUR
420619	1703937	AQUACEL ADH Foam 12.5 x 12.5 cm 1x10 CEE
420620	1703939	AQUACEL ADH Foam 12.5 x 12.5 cm 1x16 FR
420621	1703940	AQUACEL ADH Foam 17.5 x 17.5 cm 1x10 EUR
420621	1703942	AQUACEL ADH Foam 17.5 x 17.5 cm 1x10 CEE
420623	1703945	AQUACEL Foam ADH 21x21 ((1x5) EUR
420623	1703947	AQUACEL Foam ADH 21x21(1x5) CEE
420624	1703951	AQUACEL Foam ADH 25x30(1x5) CEE
420624	1703949	AQUACEL Foam ADH 25x30(1x5) EUR
420625	1703953	AQUACEL Foam ADH HEEL 19.8x14(1x5) EUR
420625	1703955	AQUACEL Foam ADH HEEL 19.8x14(1x5) CEE
420626	1703959	AQUACEL Foam SACRAL ADH 20x16.9 (1x5) CEE
420653	1704189	AQUACEL Foam ADH 21x21(1x10pk) EUR
420655	1704191	AQUACEL Foam ADH HEEL (1x10pk) EUR
420656	1704192	AQUACEL Foam SACRAL ADH (1x10pk) EUR
420626	1703957	AQUACEL Foam SACRAL ADH 20x16.9 (1x5) EUR
420680	1705400	AQUACEL Foam ADH 10X10cm (1X10) EUR
420680	1705401	AQUACEL Foam ADH 10X10cm (1X10) CEE
420680	1730133	AQUACEL FOAM ADH 10X10 CM 1X10PK STER DE
420804	1707743	AQUACEL ADH Foam 8 x 8 cm 1x10 EUR
420804	1730134	AQUACEL FOAM ADH 8X8CM 1X10PK STER DE
420828	1710041	AQUACEL Foam SACRAL ADH LRG 1x5pk EUR
421049	1710043	AQUACEL Foam SACRAL ADH LRG 1x10pk EUR
421149	1710650	AQUACEL Foam ADH 8x13cm (1x10) EUR
421149	1710651	AQUACEL Foam ADH 8x13cm (1x10) CEE
421150	1710653	AQUACEL FOAM ADH 10X20CM (1X5) EUR
421151	1710657	AQUACEL Foam ADH 10x20 CEE (1X10)
421151	1710656	AQUACEL FOAM ADH 10X20CM (1X10) EUR
421152	1710659	AQUACEL Foam ADH 10x25 EUR (1X5)
421153	1710662	AQUACEL Foam ADH 10x25 EUR (1X10)
421153	1710663	AQUACEL FOAM ADH 10X25CM (1X10) CEE
421154	1710665	AQUACEL Foam ADH 10x30 EUR (1X5)
421155	1710668	AQUACEL Foam ADH 10x30 EUR (1X10)
421155	1710669	AQUACEL Foam ADH 10x30 CEE (1X10)
421451	1713243	AQUACEL Foam ADH HEEL (1x3) ES
421452	1713241	AQUACEL Foam SACRAL ADH (1x3) ES
421494	1713244	AQUACEL Foam ADH 17.5 X 17.5 1X3 ES
422350	1723885	AQUACEL ADH Foam 15 x 15 cm 1x10 EUR

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ICC	SAP	Description
422350	1723887	AQUACEL ADH Foam 15 x 15 cm 1x10 CEE
420188	1705596	AQUACEL FOAM N/ADH 17.5 X 17.5 CM 1X 10 FR
420635	1703995	AQUACEL FOAM N/ADH 15X15(1X5) EUR
420635	1703997	AQUACEL FOAM N/ADH 15X15(1X5) CEE
420652	1704131	AQUACEL FOAM N/ADH 15X15 (1X3PK) ES
420633	1703989	AQUACEL FOAM N/ADH 10X10(1X10) EUR
420633	1703991	AQUACEL FOAM N/ADH 10X10(1X10) CEE
420633	1730135	AQUACEL FOAM N/ADH 10X10 1X10PK STER DE
420637	1704003	AQUACEL FOAM N/ADH 15X20(1X5) EUR
420637	1704005	AQUACEL FOAM N/ADH 15X20(1X5) CEE
420663	1704199	AQUACEL FOAM N/ADH 15X20(1X10) EUR
420631	1703984	AQUACEL FOAM N/ADH 5X5(1X10) EUR
420631	1703986	AQUACEL FOAM N/ADH 5X5(1X10) CEE
420636	1703999	AQUACEL FOAM N/ADH 20X20(1X5) EUR
420636	1704001	AQUACEL FOAM N/ADH 20X20(1X5) CEE
420662	1704198	AQUACEL FOAM N/ADH 20X20 (1X10PK) EUR
421156	1710671	AQUACEL FOAM N/ADH 10X20CM (1X5) EUR
413623	1710606	AQUACEL FOAM N/ADH 10X20 (1X10) CEE
422625	1729904	AQUACEL FOAM N/ADH 12.5X12.5CM 1X10PK EUR