	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

### Aquacel ConvaFiber – Sterile

### Technical Documentation MDR AWCTF 029

**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 Limited.

**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 ConvaFiber

**Basic UDI-DI:** Aquacel ConvaFiber - 768455AWC00463W

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

**EMDN Code & Description:** M040404 CELLULOSE AND/OR MODIFIED CELLULOSE DRESSINGS, NON-COMBINED OR COMBINED WITH OTHER SUBSTANCES


**Intended Purpose:** Aquacel ConvaFiber Dressings have been designed to be used as a primary dressing under the direction of a healthcare professional as per the indications for use.

**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)

	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		

Signed by:





Signer Name: Steeve Lamvohee

Signing Reason: I approve this document

Signing Time: Jun 24, 2025 | 2:13:13 PM BST

79126EF62CD04B7AA0479B4D5AA7AE98

Legal  
Manufacturer  
authorized  
signature:

Signature:

Steeve Lamvohee

Head of IC/AWC Regulatory Affairs


Date:

Jun 24, 2025


Place of Issue: Deeside, Flintshire

Appendix A: Products

ICC	SAP	Description
423988	1749837	AQUACEL CONVAFIBER 5X5CM (1X3PK) BE/NL/LU
423990	1749838	AQUACEL CONVAFIBER 10X10CM (1X3PK) BE/NL/LU
423995	1749839	AQUACEL CONVAFIBER 15X15CM (1X3PK) BE/NL/LU
423998	1749840	AQUACEL CONVAFIBER 20X24CM (1X5PK) EUR
423989	1749841	AQUACEL CONVAFIBER 5X5CM (1X10PK) EUR
423991	1749842	AQUACEL CONVAFIBER 10X10CM (1X5PK) EUR
423992	1749843	AQUACEL CONVAFIBER 10X10CM (1X10PK) EUR
423996	1749844	AQUACEL CONVAFIBER 15X15CM (1X5PK) EUR
424001	1749834	AQUACEL CONVAFIBER 4X10CM (1X10PK) EUR
424002	1749835	AQUACEL CONVAFIBER 4X20CM (1X10PK) EUR
424003	1749836	AQUACEL CONVAFIBER 4X30CM (1X10PK) EUR
423994	1749845	AQUACEL CONVAFIBER 12.5X12.5CM (1X10PK) FR
423997	1749846	AQUACEL CONVAFIBER 15X15CM (1X10PK) FR
423999	1749847	AQUACEL CONVAFIBER 20X24CM (1X10PK) FR
424000	1749848	AQUACEL CONVAFIBER 7x10CM (1X10PK) FR
423989	1749849	AQUACEL CONVAFIBER 5X5CM (1X10PK) CEE
423992	1749850	AQUACEL CONVAFIBER 10X10CM (1X10PK) CEE
423996	1749851	AQUACEL CONVAFIBER 15X15CM (1X5PK) CEE
423988	1749852	AQUACEL CONVAFIBER 5X5CM (1X3PK) ES
423990	1749853	AQUACEL CONVAFIBER 10X10CM (1X3PK) ES
423995	1749854	AQUACEL CONVAFIBER 15X15CM(1X3PK)ES
423989	1749855	AQUACEL CONVAFIBER 5X5CM (1X10PK) DE
423992	1749857	AQUACEL CONVAFIBER 10X10CM (1X10PK) DE

	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		

ICC	SAP	Description
423996	1749859	AQUACEL CONVAFIBER 15X15CM (1X5PK) DE
424001	1750129	AQUACEL CONVAFIBER 4X10CM (1X10PK) DE
424002	1750131	AQUACEL CONVAFIBER 4X20CM (1X10PK) DE
424003	1750132	AQUACEL CONVAFIBER 4X30CM (1X10PK) DE
423998	1750133	AQUACEL CONVAFIBER 20X24CM (1X5PK) DE

	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		

#### Change History:

Revision number	Date	Change	Author
1.0	Jun 24, 2025	Initial issue of CE Certificate under EU Medical Device Regulation (EU) 2017/745.	Rebecca Davies