EU Declaration of Conformity

DuoDerm Extra Thin - Hydrocolloid Dressings

Technical Documentation MDR-AWCDD-015

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
Legal Manufacturer SRN	GB-MF-000001770
Authorized Representative:	Unomedical a/s, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark
Authorised Representative SRN	DK-AR-000000941
Product Name:	Trade/ Brand Name(s): DuoDerm Extra Thin - Hydrocolloid Dressing DuoDerm Extra Thin CGF - Hydrocolloid Dressing VariHesive Extra Thin - Hydrocolloid Dressing GranuFlex Extra Thin - Hydrocolloid Dressing
Basic UDI-DI:	768455AWC00303F
GMDN Code & Name:	43186 – Exudate absorbent dressing, hydrophilic-gel, non-antimicrobial
EMDN Code & Description:	M04040301 - HYDROCOLLOID DRESSINGS, NON-COMBINED
Intended Purpose:	DuoDerm Extra Thin Dressings have been designed to be used as a primary or secondary dressing for the management of wounds and for the protection of intact skin under the direction of a healthcare professional as per the indications for use.
Device(s) & Cat. #:	Refer to Appendix A
Risk Class:	Class III as per Rules 4 and 18 in Annex VIII

TEM-FORM v3.0 This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

Notified Body:	BSI Group The Netherlands B.V. Say Building John.M. Keynesplein 9 1066 EP Amsterdam Netherlands NB Number: 2797
Certificate(s):	EC Quality Management System Certificate No. CE MDR 738968, issued by BSI (2797) in accordance with Annex IX Chapter I & III of this Regulation Certificate No. MDR 766308 DuoDERM Extra Thin, issued by BSI (2797).
Legal Manufacturer authorized signature:	**Signature:** Signed by: Steeve Lamvohee Signer Name: Steeve Lamvohee Signing Reason: I approve this document Signing Time: Sep 12, 2025 | 5:43:07 PM BST 79126EF62CD04B7AA0479B4D5AA7AE98 **Date**: Sep 12, 2025 *Steeve Lamvohee* *Head of IC/AWC Regulatory Affairs* Place of Issue:*[Deeside, Flintshire]*

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

Appendix A: List of Product Range Covered under this Declaration of Conformity

DuoDERM Extra Thin Trade/ Brand Name(s): DuoDerm Extra Thin - Hydrocolloid Dressing, DuoDerm Extra Thin CGF - Hydrocolloid Dressing, VariHesive Extra Thin - Hydrocolloid Dressing, GranuFlex Extra Thin - Hydrocolloid Dressing

ICC	SAP	Description
187951	1000900	DUODERM XTHIN DRS 7.5X7.5CM (1X5PK) EUR
187951	1000902	VARIHESIVE XTHIN DRS 7.5X7.5CM(1X5PK)DE
187954	1000905	DUODERM XTHIN DRS 10X10CM (1X5PK) EUR
187954	1000908	VARIHESIVE XTHIN DRS 10X10CM (1X5PK) DE
187956	1000916	DUODERM XTHIN DRS 15X15CM (1X5PK) EUR
187956	1000919	VARIHESIVE XTHIN DRS 15X15CM (1X5PK) DE
187956	1000921	DUODERM XTHIN DRS 15X15CM (1X5PK) IT
187959	1000928	DUODERM XTHIN DRS 5X10CM (1X10PK) EUR
187959	1000931	VARIHESIVE XTHIN DRS 5X10CM (1X10PK) DE
187961	1000937	DUODERM XTHIN DRS 5X20CM (1X10PK) EUR
187961	1000940	VARIHESIVE XTHIN DRS 5X20CM (1X10PK) DE
651008	1004123	DUODERM XTHIN DRS 10X15CM (1X5PK) EUR
187951	1013946	GRANUFLEX XTHIN DRS7.5X7.5CM(1X5)STERCEU
187954	1013947	GRANUFLEX XTHIN DRS 10X10CM(1X5)STER CEU
187956	1013948	GRANUFLEX XTHIN DRS 15X15CM(1X5)STER CEU
187959	1013949	GRANUFLEX XTHIN DRS 5X10CM(1X10)STER CEU
187961	1013950	GRANUFLEX XTHIN DRS 5X20CM(1X10)STER CEU
187905	1103432	VARIHESIVE XTHIN DRS 10X10CM (1X3PK) ES
187906	1103433	VARIHESIVE XTHIN DRS 15X15CM (1X3PK) ES
187911	1103434	VARIHESIVE XTHIN DRS 10X15CM (1X3PK) ES
187912	1103435	VARIHESIVE XTHIN DRS 15X18CM (1X3PK) ES
187914	1103437	VARIHESIVE XTHIN DRS 15X18CM (1X10PK) ES
187952	1103438	VARIHESIVE XTHIN DRS 7.5X7.5CM(1X10PK)ES
187955	1103439	VARIHESIVE XTHIN DRS 10X10CM (1X10PK) ES
187957	1103440	VARIHESIVE XTHIN DRS 15X15CM (1X10PK) ES
187959	1103441	VARIHESIVE XTHIN DRS 5X10CM (1X10PK) ES
187961	1103442	VARIHESIVE XTHIN DRS 5X20CM (1X10PK) ES
187672	1127050	DUODERM XTHIN DRS 10X15CM (1X10PK) FR
187920	1172893	VARIHESIVE XTHIN SURGICAL9X15CM1X10PK DE
187921	1172894	VARIHESIVE XTHIN SURGICAL9X25CM1X10PK DE
187920	1172896	DDERM X-THIN SURGICAL 9X15CM(1X10PK)EUR
187921	1172897	DDERM X-THIN SURGICAL 9X25CM(1X10PK)EUR
187922	1172898	DDERM X-THIN SURGICAL 9X35CM(1X10PK)EUR
187673	1173973	DUODERM XTHIN DRS OVAL (1X5PK) FR
420062	1700249	DUODERM XTHIN DRS 17.5X17.5CM(1X10PK) FR
421644	1715224	DUODERM XTHIN DRS 12.5X12.5CM(1X10PK) FR
421645	1715225	DUODERM XTHIN DRS 6X11CM (1X10PK) FR
187955	1749860	DUODERM XTHIN DRS 10X10CM (1X10PK) EUR
187957	1749861	DUODERM XTHIN DRS 15X15CM (1X10PK) EUR
401807	1749862	DUODERM XTHIN DRS 10X10CM (1X20PK) EUR
651045	1749863	DUODERM XTHIN DRS OVAL(1X10PK) EUR

TEM-FORM v3.0 This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

Revision History

Rev No	Date	Comment	Author
1	12-SEP-2025	Initial	J. Booth

This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.