

EC Declaration of Conformity

Hydrocolloid Dressings Design Dossier (DD001)

Manufacturer Name: ConvaTec Limited

Address: First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, United Kingdom

This Declaration is made under the sole responsibility of the manufacturer, ConvaTec Limited, who herewith declares that the attached list of mentioned product conforms to the applicable essential requirements and provisions of Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC) concerning medical devices.

Product Name	Trade/ Brand Name(s): DuoDERM Dressing, DuoDERM Border Dressing, DuoDERM CGF Border Dressing, Varihesive E Border Dressing, DuoDERM E Border Dressing, Granuflex E Border Dressing, Varihesive Signal Dressing, DuoDERM Signal Dressing, Granuflex Signal Dressing, DuoDERM Extra Thin Dressing, Varihesive Extra Thin Dressing, Granuflex Extra Thin Dressing, Granuflex Dressing, DuoDERM E Dressing, Varihesive E Dressing, AQUACEL Surgical Cover Dressing, DuoDERM Paste, Varihesive Paste, Granuflex Hydroactive Paste
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule (Include Sterility / Measuring if applicable)	Class III, as defined by Rule 4, 17, laid down in Annex IX of the EC Medical Device Directive (93/42/EEC)
Conformity Assessment Route	Annex II, including Section 4
Notified Body Name, Identification number Address	The British Standards Institute (BSI) 2797 BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
Authorised Representative in the European Community	Unomedical A/S, Aaholmvej 1-3, Osted, 4320, Lejre, Denmark
(QA/EC) Certification Number	ISO 13485:2016 – MD 670405 CE 00380
GMDN Code and Term title	43186, Exudate-absorbent dressing, hydrophilic gel
Harmonised Standards Applied:	BS EN 1041:2008+A1:2013, BS EN 13726-1:2002, BS EN ISO 15223-1:2016, BS EN ISO 10993-1:2009, BS EN ISO 11137-1:2015+A2:2019, BS EN ISO 11607-1:2017, BS EN ISO 11607-2:2017, BS EN ISO 13485:2016, BS EN ISO 14971:2012, BS EN ISO 22442-1:2015, BS EN ISO 22442-2:2007

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: 
 Signer Name: Gary Barrett
 Signing Reason: I approve this document
 Signed Date: 19 March 2021 17:26:00 GMT
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Gary Barrett, Vice President, Regulatory Affairs

Date: 19 March 2021

Trade/ Brand Name(s): DuoDERM Dressing, DuoDERM Border Dressing, DuoDERM CGF Border Dressing, Varihesive E Border Dressing, DuoDERM E Border Dressing, Granuflex E Border Dressing, Varihesive Signal Dressing, DuoDERM Signal Dressing, Granuflex Signal Dressing, DuoDERM Extra Thin Dressing, Varihesive Extra Thin Dressing, Granuflex Extra Thin Dressing, Granuflex Dressing, DuoDERM E Dressing, Varihesive E Dressing, AQUACEL Surgical Cover Dressing, DuoDERM Paste, Varihesive Paste, Granuflex Hydroactive Paste

ICC	Name
37300	DuoDERM Mini Hydroactive Dressing
187602	DuoDERM Dressing
187610	DuoDERM Dressing
187611	DuoDERM Dressing
187620	DuoDERM Dressing
187631	DuoDERM CGF Dressing
187632	GRANUFLEX Dressing
187638	VARIHESIVE E Dressing
187639	GRANUFLEX Dressing
187642	DuoDERM CGF Dressing
187644	GRANUFLEX Dressing
187647	DuoDERM CGF Dressing
187658	DuoDERM CGF Dressing
187660	DuoDERM CGF Dressing
187661	DuoDERM CGF Dressing
187662	GRANUFLEX Dressing
187663	DuoDERM CGF Dressing
187664	DuoDERM CGF Dressing
187665	DuoDERM CGF Dressing
187666	DuoDERM CGF Border Dressing
187667	DuoDERM CGF Border Dressing
187672	DuoDERM Extra Thin Dressing
187673	DuoDERM Extra Thin Spots
187900	DuoDERM Extra Thin Dressing
187904	VARIHESIVE Extra Thin Dressing
187905	VARIHESIVE Extra Thin Dressing
187906	VARIHESIVE Extra Thin Dressing
187911	VARIHESIVE Extra Thin Dressing
187912	VARIHESIVE Extra Thin Dressing
187914	VARIHESIVE Extra Thin Dressing
187920	DuoDERM Extra Thin Dressing
187920	VARIHESIVE Extra Thin Dressing

ICC	Name
187921	DuoDERM Extra Thin Dressing
187921	VARIHESIVE Extra Thin Dressing
187922	DuoDERM Extra Thin Dressing
187922	VARIHESIVE Extra Thin Dressing
187930	DuoDERM Hydroactive Paste
187930	Varihesive Paste
187930	Granuflex Paste
187951	DuoDERM Extra Thin Dressing
187951	VARIHESIVE Extra Thin Dressing
187951	GRANUFLEX Extra Thin Dressing
187952	VARIHESIVE Extra Thin Dressing
187954	DuoDERM Extra Thin Dressing
187954	VARIHESIVE Extra Thin Dressing
187954	GRANUFLEX Extra Thin Dressing
187955	DuoDERM Extra Thin
187955	VARIHESIVE Extra Thin Dressing
187956	DuoDERM Extra Thin Dressing
187956	VARIHESIVE Extra Thin Dressing
187956	GRANUFLEX Extra Thin Dressing
187957	DuoDERM Extra Thin Dressing
187957	VARIHESIVE Extra Thin Dressing
187959	DuoDERM Extra Thin Dressing
187959	VARIHESIVE Extra Thin Dressing
187959	GRANUFLEX Extra Thin Dressing
187961	DuoDERM Extra Thin
187961	VARIHESIVE Extra Thin Dressing
187961	GRANUFLEX Extra Thin Dressing
187970	DuoDERM CGF Border Dressing
187971	DuoDERM CGF Border Dressing
187972	DuoDERM CGF Border Dressing
187973	DuoDERM CGF Border
187974	DuoDERM CGF Border Dressing
401807	DuoDERM Extra Thin Dressing
403326	DuoDERM Signal Border Dressing
403327	DuoDERM Signal Border Dressing
403328	DuoDERM Signal Border Dressing
403332	DuoDERM Signal Border Dressing

ICC	Name
410500	DuoDERM Signal Border Dressing
410501	DuoDERM Signal Border Dressing
410507	DuoDERM Signal Border Dressing
410508	DuoDERM Signal Border Dressing
410510	DuoDERM Signal Border Dressing
412017	Aquacel Surgical Cover Dressing
412018	Aquacel Surgical Cover Dressing
412019	Aquacel Surgical Cover Dressing
412020	Aquacel Surgical Cover Dressing
420061	DuoDERM Extra Thin Dressing
420062	DuoDERM Extra Thin Dressing
420063	DuoDERM Extra Thin Dressing
420064	DuoDERM Extra Thin Dressing
420669	Aquacel Surgical Cover Dressing
421644	DuoDERM Extra Thin Dressing
421645	DuoDERM Extra Thin Dressing
650902	VARIHESIVE CGF Border Dressing
650904	VARIHESIVE CGF Border Dressing
650921	VARIHESIVE CGF Border Dressing
650922	VARIHESIVE CGF Border Dressing
650924	VARIHESIVE CGF Border Dressing
651008	DuoDERM Extra Thin Dressing
651008	VARIHESIVE Extra Thin Dressing
651022	GRANUFLEX Bordered Dressing
651023	GRANUFLEX Bordered Dressing
651045	DuoDERM Extra Thin Spots

ConvaTec

Deklaracja zgodności WE
Dokumentacja projektowa – opatrunki hydrożelowe (DD001)

Wytwórca: ConvaTec Limited
Adres: First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
Wielka Brytania

Niniejsza deklaracja zostaje wydana na wyłączną odpowiedzialność wytwórcy, ConvaTec Limited, który niniejszym oświadcza, że wyroby wskazane na załączonej liście spełniają odnośne zasadnicze wymagania i postanowienia dyrektywy 93/42/EWG w sprawie wyrobów medycznych, zmienionej dyrektywą 2007/47/WE w sprawie wyrobów medycznych.

Nazwa wyrobu	Nazwa handlowa (nazwy handlowe) / marka (marki): DuoDERM Dressing, DuoDERM Border Dressing, DuoDERM CGF Border Dressing, Varihesive E Border Dressing, DuoDERM E Border Dressing, Granuflex E Dressing, Varihesive Signal Dressing, DuoDERM Signal Dressing, Granuflex Signal Dressing, DuoDERM Extra Thin Dressing, Varihesive Extra Thin Dressing, Granuflex Extra Thin Dressing, Granuflex Dressing, DuoDERM E Dressing, Varihesive E Dressing, AQUACEL Surgical Cover Dressing, DuoDERM Paste, Varihesive Paste, Granuflex Hydroactive Paste
Kody wyrobów	Lista odpowiednich kodów wyrobów znajduje się w załączeniu.
Klasyfikacja i reguła	Klasa III zgodnie z definicją zawartą w załączniku IX, reguła 4, 17, dyrektywy WE w sprawie wyrobów medycznych (93/42/EWG)
Procedura oceny zgodności	Załącznik II, w tym ust. 4
Jednostka notyfikowana Nazwa Numer identyfikacyjny Adres	British Standards Institute (BSI) 2797 BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Holandia
Upoważniony przedstawiciel w Unii Europejskiej	Unomedical A/S, Aaholmvej 1-3, Osted, 43230, Lejre, Dania
Numer Certyfikatu (QA/WE)	ISO 13485:2016 – MD 670405 CE 00364
Kod i opis rodzajowy wg GMDN	43186, opatrunek pochłaniający wysięk, hydrożelowy
Stosowane normy zharmonizowane:	BS EN 1041:2008+A1:2013, BS EN 13726-1:2002, BS EN ISO 15223-1:2016, BS EN ISO 10993-1:2009, BS EN ISO 11137-1:2015+A2:2019, BS EN ISO 11607-1:2017, BS EN ISO 11607-2:2017, BS EN ISO 13485:2016, BS EN ISO 14971:2012, BS EN ISO 22442-1:2015, BS EN ISO 22442-2:2007

Wydano w Deeside, w Wielkiej Brytanii.

Podpisano w imieniu i na rzecz spółki ConvaTec Limited

Imię i nazwisko: /-/

Data: 19/ marca/ 2021

Gary Barrett, Vice President, Regulatory Affairs

Wydanie: 6

Data: 19 marca 2021 r.

Trade/ Brand Name(s):

Nazwy handlowe

DuoDERM Dressing, DuoDERM Border Dressing, DuoDERM CGF Border Dressing, Varihesive E Border Dressing, DuoDERM E Border Dressing, Granuflex E Border Dressing, Varihesive Signal Dressing, DuoDERM Signal Dressing, Granuflex Signal Dressing, DuoDERM Extra Thin Dressing, Varihesive Extra Thin Dressing, Granuflex Extra Thin Dressing, Granuflex Dressing, DuoDERM E Dressing, Varihesive E Dressing, AQUACEL Surgical Cover Dressing, DuoDERM Paste, Varihesive Paste, Granuflex Hydroactive Paste

Kod / nazwa

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