

EC Declaration of Conformity

Hydrocolloid Dressings Design Dossier (DD001)

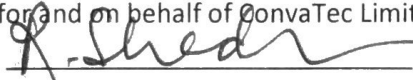
Manufacturer Name: ConvaTec Limited,
 Address: First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
 United Kingdom

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 CGF, DuoDERM CGF Border, Granuflex, Varihesive, Varihesive Extra Thin, DuoDERM Extra Thin, DuoDERM Signal Border, DuoDERM Dressing, DuoDERM Paste, Granuflex Paste, Varihesive 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, 43230, 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:	EN ISO 10993-1: 2009, EN ISO 14971: 2012, EN 1041: 2008, EN ISO 14155: 2011, ISO 11607-1: 2009, ISO 11607-2: 2006, EN 62366: 2008

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: 

Date: 18/MAR/2020

Rebecca Sheridan, Senior Director, AWC Franchise RAQA

Trade/ Brand Name(s): DuoDERM CGF, DuoDERM CGF Border, Granuflex, Varihesive, Varihesive Extra Thin, DuoDERM Extra Thin, DuoDERM Signal Border, DuoDERM Dressing, DuoDERM Paste, Granuflex Paste, Varihesive Paste

Product Codes	Product Description
DuoDERM Paste (Varihesive, Granuflex)	
187930	DuoDerm Paste, 30g
187930	Varihesive Paste, 30g
187930	Granuflex Hydrocolloid Paste, 30g
DuoDERM CGF (Varihesive, Granuflex E)	
187665	DuoDERM E Dressing, 20x20cm
187664	DuoDERM CGF Dressing, 10x10cm
187663	Varihesive E Dressing, 20x20cm
187661	DuoDERM CGF Dressing, 15x15cm
187661	Varihesive E Dressing, 15x15cm
187660	DuoDERM CGF Dressing, 10x10cm
187660	Varihesive E Dressing, 10x10cm
187658	DuoDERM CGF Dressing, 10x10cm
187631	Granuflex Dressing, 15x20cm
187632	Granuflex Dressing, 15x15cm
187647	DuoDERM E Dressing, 15x15cm
187642	DuoDERM CGF Dressing, 20x20cm
187632	Varihesive E Dressing, 15x15cm
187632	Granuflex Dressing, 15x15cm
187639	DuoDERM E Dressing, 10x10cm
187639	Granuflex Dressing, 10x10cm
187644	DuoDERM CGF Dressing, 20x30cm
187644	Granuflex Dressing, 20x30cm
187662	DuoDERM CGF Dressing, 20x20cm
187662	Granuflex Dressing, 20x20cm
187638	Varihesive E Dressing, 10x10cm
650924	Varihesive CGF Border Dressing, 10x13cm
650922	Varihesive CGF Border Dressing, 10x10cm
650921	Varihesive CGF Border Dressing, 6x6cm
650904	Varihesive CGF Border Dressing, 10x13cm
650902	Varihesive CGF Border Dressing, 10x10cm

187667	DuoDERM CGF Border Dressing, 15x18cm
187666	DuoDERM CGF Border Dressing, 14x14cm
187970	DuoDERM CGF Border Dressing, 6x6cm
187970	Granuflex E Border Dressing, 6x6cm
187971	DuoDERM CGF Border Dressing, 10x10cm
187971	Varihesive CGF Border Dressing, 10x10cm
187971	Granuflex E Border Dressing, 10x10cm
187972	DuoDERM CGF Border Dressing, 15x15cm
187972	Granuflex E Border Dressing, 15x15cm
187973	DuoDERM CGF Border Dressing, 10x13cm
187973	Granuflex E Border Dressing, 10x13cm
187974	DuoDERM CGF Border Dressing, 15x18cm
187974	Varihesive CGF Border Dressing, 15x18cm
187974	Granuflex E Border Dressing, 15x18cm
651023	Granuflex E Border Dressing, 10x13cm
651022	Granuflex E Border Dressing, 10x10cm
DuoDERM Extra-Thin (ActiDERM, Granuflex Extra Thin, Varihesive Extra-Thin)	
187922	DuoDERM Extra-Thin Surgical Dressing, 9x35cm
187922	Varihesive Extra-Thin Surgical Dressing, 9x35cm
187921	DuoDERM Extra-Thin Surgical Dressing, 9x25cm
187921	Varihesive Extra-Thin Surgical Dressing, 9x25cm
187920	DuoDERM Extra-Thin Surgical Dressing, 9x15cm
187920	Varihesive Extra-Thin Surgical Dressing, 9x15cm
187951	Varihesive Extra-Thin Dressing, 7.5x7.5cm
187951	Granuflex Extra-Thin Dressing, 7.5x7.5cm
187954	DuoDERM Extra-Thin Dressing, 10x10cm
187954	Granuflex Extra-Thin Dressing, 10x10cm
187956	DuoDERM Extra-Thin Dressing, 15x15cm
187956	Varihesive Extra-Thin Dressing, 15x15cm
187956	Granuflex Extra-Thin Dressing, 15x15cm
187957	DuoDERM Extra-Thin Dressing, 15x15cm
187959	DuoDERM Extra-Thin Dressing, 5x10cm
187959	Granuflex Extra-Thin Dressing, 5x10cm
401807	DuoDERM Extra-Thin Dressing, 10x10cm
187900	DuoDERM Extra-Thin Dressing, 5x10cm
187904	Varihesive Extra-Thin Dressing, 7.5x7.5cm
187905	Varihesive Extra-Thin Dressing, 10x10cm

187906	Varihesive Extra-Thin Dressing, 15x15cm
187911	Varihesive Extra-Thin Dressing, 10x15cm
187912	Varihesive Extra-Thin Dressing, 15x18cm
187914	Varihesive Extra-Thin Dressing, 15x18cm
187952	Varihesive Extra-Thin Dressing, 7.5x7.5cm
187955	Varihesive Extra-Thin Dressing, 10x10cm
187961	Varihesive Extra-Thin Dressing, 5x20cm
187961	Granuflex Extra-Thin Dressing, 5x20cm
420061	DuoDERM Extra-Thin Dressing, 12.5x12.5cm
420062	DuoDERM Extra-Thin Dressing, 17.5x17.5cm
420063	DuoDERM Extra-Thin Dressing, 6x11cm
420064	DuoDERM Extra-Thin Dressing, 6x21cm
651008	Varihesive Extra-Thin Dressing, 10x15cm
421644	DuoDERM Extra-Thin Dressing, 12.5x12.5cm
421645	DuoDERM Extra-Thin Dressing, 6x11cm
DuoDERM Extra-Thin (OTC)	
412021	DuoDERM Extra-Thin Dressing, 10x10cm
412021	Granuflex Extra-Thin Dressing, 10x10cm
413431	DuoDERM Extra-Thin Dressing, 10x10cm
413432	DuoDERM Extra-Thin Dressing, 5x10cm
413433	DuoDERM Extra-Thin Dressing, 5x10cm
DuoDERM Signal (Granuflex Signal, Varihesive Signal)	
410510	DuoDERM Signal Dressing, 11x19cm
410508	DuoDERM Signal Dressing, 20x22.5cm
410507	DuoDERM Signal Dressing, 18.5x19.5cm
410501	DuoDERM Signal Dressing, 20x22.5cm
410501	Granuflex Signal Dressing, 20x22.5cm
410501	Varihesive Signal Dressing, 20x22.5cm
410500	DuoDERM Signal Dressing, 18.5x19.5cm
410500	Granuflex Signal Dressing, 18.5x19.5cm
410500	Varihesive Signal Dressing, 18.5x19.5cm
403332	DuoDERM Signal Dressing, 15x18cm
403328	DuoDERM Signal Dressing, 20x20cm
403328	Granuflex Signal Dressing, 20x20cm
403328	Varihesive Signal Dressing, 20x20cm
403327	DuoDERM Signal Dressing, 14x14cm
403327	Granuflex Signal Dressing, 14x14cm

403327	Varihesive Signal Dressing, 14x14cm
403326	DuoDERM Signal Dressing, 10x10cm
403326	Granuflex Signal Dressing, 10x10cm
403326	Varihesive Signal Dressing, 10x10cm
DuoDERM Wafer (Varihesive, Granuflex, DuoDERM Classic/Hydroactive)	
187620	DuoDERM Dressing, 20x20cm
187611	DuoDERM Dressing, 10x10cm
187610	DuoDERM Dressing, 10x10cm
187602	DuoDERM Dressing, 10x10cm
37300	DuoDERM Border Dressing, 5x5cm
DuoDERM Extra-Thin	
187672	DuoDERM Extra-Thin Dressing, 10x15cm
187673	DuoDERM Extra-Thin Dressing, Oval
651045	DuoDERM Extra-Thin Dressing, Oval

Hydrocolloid Dressings

History Page

Issue number	Date	Comment
1	10 MAY 2019	Initial Release of new format DoC
2	20 JUN 2019	DoC updated to reflect the BSI review of the supplement Dossier for the Haina Expansion Program
3	17 DEC 2019	Update for alignment with Draft EC Cert
4	31 JAN 2020	Removed CombiDERM Product Codes
5	17 MAR 2020	Update to include line items for alternate product names