

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.****CE 00380****Issued To:**

**ConvaTec Limited  
First Avenue  
Deeside Industrial Park  
Deeside  
Flintshire  
CH5 2NU  
United Kingdom**

**In respect of:**

**DuoDERM Hydroactive Paste  
DuoDERM Extra Thin  
DuoDERM Border  
DuoDERM Signal  
DuoDERM CGF Border  
Aquacel Hydrofiber Surgical Cover Dressing**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

**First Issued: 1994-12-09****Date: 2021-03-15****Expiry Date: 2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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### DuoDERM Hydroactive Paste

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187930	DuoDERM Hydroactive Paste (Varihesive, Granuflex)	30g 1 Pack Size	DuoDERM Paste is intended to be used in association with a secondary dressing such as DuoDERM Dressings for the management of exuding dermal ulcers, including full-thickness wounds such as leg ulcers, pressure ulcers, and diabetic ulcers. The paste aids in absorption of excessive exudate and extends the life of the secondary dressing.	III

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### DuoDERM Extra-Thin

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187922	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing	9cm x 35cm 10 Pack Size	Chronic Wounds - Dry to lightly exuding wounds, e.g., leg ulcers, superficial pressure sores.	III
187921	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing	9cm x 25cm 10 Pack Size	Acute Wounds - Surgical wounds, e.g., post-operative wounds, minor burns, abrasions or lacerations. May be used as a secondary dressing in combination with other modern wound care products, e.g., alginates, hydrogels.	III
187920	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing	9cm x 15 cm 10 Pack Size	Protective Dressing - indicated for use to protect intact skin from medical device related pressure injury resulting from the use of devices such as face masks, glasses and ventilation tubing.	III
187951	DuoDERM Extra Thin Dressing VARIHESIVE Extra Thin Dressing Varihesive Extra Thin Dressing	7.5cm x 7.5cm 5 Pack Size	Dermatological indications - Indicated for use either alone or with topical steroids in the management of psoriasis or other recalcitrant conditions where the enhanced response offered by occlusion is recommended by the physician. When used together with topical medication, this product should be used under the direction of a physician.	III
187954	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing Granuflex Extra Thin Dressing	10cm x 10cm 5 Pack Size		III
187956	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing Granuflex Extra Thin Dressing	15cm x 15cm 5 Pack Size		III
187957	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing	15cm x 15cm 10 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187959	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing Granuflex Extra Thin Dressing	5cm x 10cm 10 Pack Size	Chronic Wounds - Dry to lightly exuding wounds, e.g., leg ulcers, superficial pressure sores.	III
401807	DuoDERM Extra Thin Dressing	10cm x 10cm 20 Pack Size	Acute Wounds - Surgical wounds, e.g., post-operative wounds, minor burns, abrasions or lacerations. May be used as a secondary dressing in combination with other modern wound care products, e.g., alginates, hydrogels.  Protective Dressing - indicated for use to protect intact skin from medical device related pressure injury resulting from the use of devices such as face masks, glasses and ventilation tubing.  Dermatological indications - Indicated for use either alone or with topical steroids in the management of psoriasis or other recalcitrant conditions where the enhanced response offered by occlusion is recommended by the physician. When used together with topical medication, this product should be used under the direction of a physician.	III
187900	DuoDERM Extra Thin Dressing	5cm x 10cm 20 Pack Size		III
187904	Varihesive Extra Thin Dressing	7.5cm x 7.5cm 3 Pack Size		III
187905	Varihesive Extra Thin Dressing	10cm x 10cm 3 Pack Size		III
187906	Varihesive Extra Thin Dressing	15cm x 15cm 3 Pack Size		III
187911	Varihesive Extra Thin Dressing	10cm x 15cm 3 Pack Size		III
187912	Varihesive Extra Thin Dressing	15cm x 18cm 3 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187914	Varihesive Extra Thin Dressing	15cm x 18cm 3 Pack Size	Chronic Wounds - Dry to lightly exuding wounds, e.g., leg ulcers, superficial pressure sores.	III
187952	Varihesive Extra Thin Dressing	7.5cm x 7.5cm 10 Pack Size	Acute Wounds - Surgical wounds, e.g., post-operative wounds, minor burns, abrasions or lacerations. May be used as a secondary dressing in combination with other modern wound care products, e.g., alginates, hydrogels.	III
187955	DuoDERM Extra Thin Varihesive Extra Thin Dressing	10cm x 10cm 10 Pack Size	Protective Dressing - indicated for use to protect intact skin from medical device related pressure injury resulting from the use of devices such as face masks, glasses and ventilation tubing.	III
187961	DuoDERM Extra Thin Varihesive Extra Thin Dressing Granuflex Extra Thin Dressing	5cm x 20cm 10 Pack Size	Dermatological indications - Indicated for use either alone or with topical steroids in the management of psoriasis or other recalcitrant conditions where the enhanced response offered by occlusion is recommended by the physician. When used together with topical medication, this product should be used under the direction of a physician.	III
420061	DuoDERM Extra Thin Dressing	12.5cm x 12.5cm 16 Pack Size		III
420062	DuoDERM Extra Thin Dressing	17.5cm x 17.5cm 10 Pack Size		III
420063	DuoDERM Extra Thin Dressing	6cm x 11cm 16 Pack Size		III
420064	DuoDERM Extra Thin Dressing	6cm x 21cm 16 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
651008	DuoDERM Extra Thin Dressing Varihesive Extra Thin Dressing	10cm x 15cm 5 Pack Size	Chronic Wounds - Dry to lightly exuding wounds, e.g., leg ulcers, superficial pressure sores.	III
421644	DuoDERM Extra Thin Dressing	12.5cm x 12.5cm 10 Pack Size	Acute Wounds - Surgical wounds, e.g., post-operative wounds, minor burns, abrasions or lacerations. May be used as a secondary dressing in combination with other modern wound care products, e.g., alginates, hydrogels.	III
421645	DuoDERM Extra Thin Dressing	6cm x 11cm 3 Pack Size	Protective Dressing - indicated for use to protect intact skin from medical device related pressure injury resulting from the use of devices such as face masks, glasses and ventilation tubing.	III
187672	DuoDERM Extra Thin Dressing	10cm x 15cm 10 Pack Size	Dermatological indications - Indicated for use either alone or with topical steroids in the management of psoriasis or other recalcitrant conditions where the enhanced response offered by occlusion is recommended by the physician. When used together with topical medication, this product should be used under the direction of a physician.	III
187673	DuoDERM Extra Thin Spots	4.4cm x 3.8cm 5 Pack Size		III
651045	DuoDERM Extra Thin Spots	4.4cm x 3.8cm 10 Pack Size		III

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### DuoDERM

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187620	DuoDERM Dressing	20cm x 20cm 3 Pack Size	DuoDERM Dressings are indicated for chronic wounds: dermal ulcers (including full thickness wounds), pressure ulcers (Stage I - IV), leg ulcers; and acute wounds: superficial wounds (e.g. minor abrasions), second degree burns, donor sites.	III
187611	DuoDERM Dressing	10cm x 10cm 20 Pack Size		III
187610	DuoDERM Dressing	10cm x 10cm 5 Pack Size		III
187602	DuoDERM Dressing	10cm x 10cm 2 Pack Size		III

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### DuoDERM Border

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
37300	DuoDERM Border Dressing	5cm x 5cm 50 Pack Size	DuoDERM Border Dressings are indicated for chronic wounds: dermal ulcers (including full thickness wounds), pressure ulcers (Stage I - IV), leg ulcers; and acute wounds: superficial wounds (e.g. minor abrasions), second degree burns, donor sites.	III

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### DuoDERM Signal

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
410510	DuoDERM Signal Border Dressing	Oval 11cm x 19cm 5 Pack Size	Under the supervision of a healthcare professional, DuoDERM Signal may be used for wounds such as: leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers and pressure ulcers/sores (partial & full thickness); surgical wounds (post-operative left to heal by secondary intention, donor sites, dermatological excisions); second degree burns; traumatic wounds including: abrasions; lacerations; minor cuts.	III
410508	DuoDERM Signal Border Dressing	20cm x 22.5cm 10 Pack Size		III
410507	DuoDERM Signal Border Dressing	18.5cm x 19.5cm 10 Pack Size		III
410501	DuoDERM Signal Border Dressing	Sacral 20cm x 22.5cm 5 Pack Size		III
410500	DuoDERM Signal Border Dressing	Heel 18.5cm x 19.5cm 5 Pack Size		III
403332	DuoDERM Signal Border Dressing	15cm x 18cm 5 Pack Size		III
403328	DuoDERM Signal Border Dressing	20cm x 20cm 5 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
403327	DuoDERM Signal Border Dressing	14cm x 14cm 5 Pack Size	Under the supervision of a healthcare professional, DuoDERM Signal may be used for wounds such as: leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers and pressure ulcers/sores (partial & full thickness); surgical wounds (post-operative left to heal by secondary intention, donor sites, dermatological excisions); second degree burns; traumatic wounds including: abrasions; lacerations; minor cuts.	III
403326	DuoDERM Signal Border Dressing	10cm x 10cm 5 Pack Size		III

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### DuoDERM CGF

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187665	DuoDERM CGF Dressing	20cm x 20cm 10 Pack Size	DuoDERM CGF Dressings are indicated for chronic wounds: pressure ulcers (Stage I - IV), leg ulcers; and acute wounds: traumatic wounds (minor abrasions, lacerations), burns (first and second degree), dermatological excisions, surgical wounds (post-operative wounds, donor sites).	III
187664	DuoDERM CGF Dressing	10cm x 10cm 16 Pack Size		III
187663	DuoDERM CGF Dressing	20cm x 20cm 3 Pack Size		III
187661	DuoDERM CGF Dressing	15cm x 15cm 5 Pack Size		III
187660	DuoDERM CGF Dressing	10cm x 10cm 5 Pack Size		III
187658	DuoDERM CGF Dressing	10cm x 10cm 20 Pack Size		III
187631	DuoDERM CGF Dressing	15cm x 20cm 10 Pack Size		III
187647	DuoDERM CGF Dressing	15cm x 15cm 3 Pack Size		III
187642	DuoDERM CGF Dressing	20cm x 30cm 3 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187632	GRANUFLEX Dressing	15cm x 15cm 10 Pack Size	DuoDERM CGF Dressings are indicated for chronic wounds: pressure ulcers (Stage I - IV), leg ulcers; and acute wounds: traumatic wounds (minor abrasions, lacerations), burns (first and second degree), dermatological excisions, surgical wounds (post-operative wounds, donor sites).	III
187639	GRANUFLEX Dressing	10cm x 10cm 10 Pack Size		III
187644	GRANUFLEX Dressing	20cm x 30cm 5 Pack Size		III
187662	GRANUFLEX Dressing	20cm x 20cm 5 Pack Size		III
187638	VARIHESIVE E Dressing	10cm x 10cm 3 Pack Size		III

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### DuoDERM CGF Border

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187667	DuoDERM CGF Border Dressing	15cm x 18cm 16 Pack Size	DuoDERM CGF Border Dressings are indicated for the following wound types: chronic wounds -dermal ulcers (including full thickness wounds), pressure ulcers (stage I-IV), leg ulcers; and acute wounds-superficial wounds (e.g. minor abrasions), second degree burns, donor sites.	III
187666	DuoDERM CGF Border Dressing	14cm x 14cm 16 Pack Size		III
650924	VARIHESIVE CGF Border Dressing	10cm x 13cm 10 Pack Size		III
650922	VARIHESIVE CGF Border Dressing	10cm x 10cm 10 Pack Size		III
650921	VARIHESIVE CGF Border Dressing	6cm x 6cm 10 Pack Size		III
650904	VARIHESIVE CGF Border Dressing	10cm x 13cm 3 Pack Size		III
650902	VARIHESIVE CGF Border Dressing	10cm x 10cm 3 Pack Size		III
187970	DuoDERM CGF Border Dressing	6cm x 6cm 5 Pack Size		III
187971	DuoDERM CGF Border Dressing	10cm x 10cm 5 Pack Size		III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
187972	DuoDERM CGF Border Dressing	15cm x 15cm 5 Pack Size	DuoDERM CGF Border Dressings are indicated for the following wound types: chronic wounds -dermal ulcers (including full thickness wounds), pressure ulcers (stage I-IV), leg ulcers; and acute wounds-superficial wounds (e.g. minor abrasions), second degree burns, donor sites.	III
187973	DuoDERM CGF Border Dressing	10cm x 13cm 5 Pack Size		III
187974	DuoDERM CGF Border	15cm x 18cm 5 Pack Size		III
651023	GRANUFLEX Border Dressing	10cm x 13cm 10 Pack Size		III
651022	GRANUFLEX Border Dressing	10cm x 10cm 10 Pack Size		III

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### Aquacel Hydrofiber Surgical Cover Dressing

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Class
412017	Aquacel Surgical Cover Dressing	10cm x 9cm 10 Pack Size	Under the supervision of a healthcare professional, these dressings may be used for the management of wounds healing by primary intent (e.g. traumatic and elective post-operative wounds/ incisions).	III
412018	Aquacel Surgical Cover Dressing	15cm x 9cm 10 Pack Size		III
412019	Aquacel Surgical Cover Dressing	25cm x 9cm 10 Pack Size		III
420669	Aquacel Surgical Cover Dressing	30cm x 9cm 10 Pack Size		III
412020	Aquacel Surgical Cover Dressing	35cm x 9cm 10 Pack Size		III

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## Certificate History

Date	Reference Number	Action
9 December 1994	ME 000552	First issue.
13 August 1996	MD 000161	Addition of CombiDERM.
16 September 1997	MD 000161	Addition of alternative manufacturing site for CombiDERM. Change of absorbent pad material for CombiDERM.
5 January 1999	MD 000161/1	Addition of CombiDERM N (SupraDERM).
22 December 1999	10008939	Certificate renewal.
23 December 2002	10046008	Change of wound contact component and change in shelf life for CombiDERM and CombiDERM N.
25 June 2003	10049247	Addition of DuoDERM Signal, revised labelling for DuoDERM Extra Thin, shelf-life extension for CombiDERM and CombiDERM N.
26 September 2003	10052680	Addition of three DuoDERM Extra Thin Surgical sizes.
12 August 2004	10060159	Addition of one size (oval shape) to DuoDERM Signal range.
16 February 2005	10063691	Certificate renewal and change of supplier of the raw material (Polyisobutylene).
11 February 2010	10110599	Certificate renewal.

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Date	Reference Number	Action
27 May 2010	10104722	Addition of Aquacel Hydrofiber Surgical Cover Dressing.
08 October 2010	10117168	Addition of four new DuoDERM Extra Thin sizes to range.
17 October 2011	10130991	Addition of 30cm x 9cm variant to Aquacel Surgical Cover Dressing range.
24 August 2012	10134750	Addition of four new DuoDERM Extra Thin pack configurations (OTC). Administrative update to certificate format.
17 December 2013	10143085	Addition of ConvaTec Deeside as an alternative site for stitch bonding and extension to shelf-life to 3 years for Aquacel Hydrofiber Surgical Cover Dressing.
10 December 2014	10152073	Product Description table updated to include alternative trade names. Certificate renewal.
17 November 2016	10164268	Removal of hot melt tie layer in Duoderm CGF Dressing. Out sourcing adhesive tie layer coating process to PSI for Duoderm Classic and Hydroactive. Change in pack count for Duoderm Extra Thin and Duoderm CGF to 10 for French market. Reduced thickness of PU layer in Duoderm Extra Thin dressing. Administrative change to list all product codes on certificate.
10 May 2017	10170558	Transfer of crimp & cut, ABCO rotary table, and packaging processes for AQUACEL Hydrofiber Surgical Dressing to ConvaTec Dominican Republic (Haina).

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**First Avenue**  
**Deeside Industrial Park**  
**Deeside**  
**Flintshire**  
**CH5 2NU**  
**United Kingdom**

## Certificate History

Date	Reference Number	Action
07 September 2017	8767803	Transfer of the complete end to end process for AQUACEL Hydrofiber Surgical Dressing to ConvaTec Dominican Republic (Haina).
	8768187	Transfer of the complete end to end manufacture for a subset of DuoDerm product codes to ConvaTec Dominican Republic (Haina). Addition of product code 187900 (DuoDerm Extra Thin).
28 November 2017	8796632	Addition of alternate nylon yarn supplier (Rex H Perkins).
27 April 2018	8854402	Transfer of the complete end to end manufacture for a subset of DuoDerm product codes to ConvaTec Dominican Republic (Haina).
24 August 2018	8937477	Change of the anti-stat used by the supplier of the Lyocell tow affecting the Aquacel Hydrofiber Surgical Dressing (all codes).
07 March 2019	7779272	Traceable to NB 0086.
18 June 2019	9715285	Addition of a new manufacturing line (ELC 11) and a change in Durahesive mixing parameters for all Duoderm dressings and Aquacel Surgical Cover Dressings; addition of a new packaging line (Doyen B) for Duoderm Extra Thin/Transparent Dressings at the ConvaTec Dominican Republic manufacturing site.

First Issued: **1994-12-09**Date: **2021-03-15**Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.



# EC Design-Examination Certificate

## Supplementary Information to CE 00380

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## Certificate History

Date	Reference Number	Action
06 December 2019	9753904	Certificate renewal Removal of CombiDERM and CombiDERM N due to discontinuation. Reworking of scope to list product families. Update of device listing to include intended use.
17 April 2020	3068597	The addition of an alternative release liner supplier (Gascogne Flexible, Dax, France) for DuoDERM and Aquacel Surgical.
Current	3261854	Addition of 'protective' indications for DuoDERM Extra Thin, Granuflex Extra Thin & Varihesive Extra Thin. Removal of DuoDERM Extra Thin (OTC) codes due to discontinuation. Addition of EU representative Unomedical A/S Denmark. Update to device tables. Scope update: Change DuoDERM Extra-Thin (ActiDERM) to DuoDERM Extra Thin.

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