

June 28, 2017

To whom it may concern,

Attached is the Declaration of Conformity and associated Product List which is the basis of the CE Marking for the Biodermis Silicone Gel Sheeting. The Silicone Gel sheeting is a Class 1/Other product, as classified by Annex IX of the EC Directive. There is, therefore, no CE certificate from a Notified Body for this product.

Best Regards,



Martin Mitchell
President

**BIODERMIS
DECLARATION OF CONFORMITY
Silicone Gel Sheeting**

We hereby declare that the following distributed CE marked products, specified in the annexed product list, conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council directive 93/42/EEC of June 1993, concerning medical devices.

In addition, we ensure and declare that the CE marked products, as mentioned and falling within Class 1/Other (non-sterile, non-measurable) (as determined by Annex IX of the EC-Directive), meet the provisions of the EC-Directive which apply to them, including Annex I, Essential Requirements, and the requirements of Annex VII, EC Declaration of Conformity.

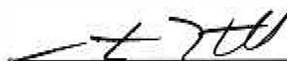
This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex VII of the EC-Directive.

This declaration is supported by the ISO 13485:2003, Quality System Certificate with reference number FM508871, issued on March 26, 2007, and delivered by BSI Management Systems.

This Declaration of Conformity covers Biodermis Silicone Gel Sheeting as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Biodermis
1820 WHITNEY MESA DRIVE
HENDERSON, NEVADA 89014, USA

Issued in Henderson, NV
June 28, 2017



Martin Mitchell, President

EU Representative:
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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BIODERMIS™

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BIODERMIS PRODUCT LIST Silicone Gel Sheeting & Accessories

This product list belongs to the Declaration of Conformity identified by Biodermis and specifies the CE marked products concerned that Biodermis intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The following list identifies the products by name and catalog number. *Time related information:* CE mark applied to all Gel Sheeting after September 15, 2000.

<u>Product Name</u>	<u>Product Code</u> Epi-Derm	<u>Product Code</u> TNT Epiderm	<u>Product Code</u> Fabric Epiderm	<u>Product Code</u> DermaSof	<u>Product Code</u> TopiGel
GEL SHEET					
Single Sheet	EDG-146	EDGTNT-146	FDG-146	DSG-146	TPG-146
Five Pack	EDG-46	EDGTNT-46	FDG-46	DSG-46	TPG-46
Large Sheet	EDG-1116	EDGTNT-1116	FDG-1116	DSG-1116	TPG-1116
Five Pack	EDG-5116	EDGTNT-5116	FDG-5116		
3 Sheets			FDG-3		
6 Sheets			FDG-6		
15 Sheets			FDG-15		
30 Sheets			FDG-30		
GEL STRIP					
2 Strips	EDG-1112	EDGTNT-1112	FDG-1112	DSG-1112	TPG-1112
10 Strips	EDG-5112	EDGTNT-5112	FDG-5112		
GEL C-STRIP					
1 Strip	EDG-1106	EDGTNT-1106	FDG-1106	DSG-1106	TPG-1106
5 Strips	EDG-5106	EDGTNT-5106	FDG-5106		
GEL PATCH					
2 Patches	EDG-123	EDGTNT-123	FDG-123	DSG-123	TPG-123
10 Patches	EDG-5123	EDGTNT-5123	FDG-5123		
GEL AREOPEXY					
2 Areopexy	ELP-1	ELPTNT-1	FLP-1	DLP-1	TLP-1
10 Pair Areopexy	ELP-51	ELPTNT-51	FLP-51		
GEL MASTOPEXY FORM					
1 each Left & Right	EMP-1	EMPTNT-1	FMP-1	DMP-1	TPG-1
10 Pair Left & Right	EMP-51	EMPTNT-51	FMP-51		
GEL AREOLA CIRCLES					
2 Circles	EAC-1	EACTNT-1	FAC-1	DAC-1	TAC-1
10 Circles	EAC-51	EACTNT-51	FAC-51		
GEL EPI-TAB SQUARES					
6 Squares	EPT-S	EPTTNT-S	FPT-S		
30 Squares	EPT-S51	EPTTNT-S51	FPT-S51		

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Time related information: CE mark applied to all Gel Sheeting after September 15, 2000.

<u>Product Name</u>	<u>Product Code</u> Epiderm	<u>Product Code</u> TNT Epiderm	<u>Product Code</u> Fabric Epiderm	<u>Product Code</u> DermaSof	<u>Product Code</u> TopiGel
GEL EPI-TAB CIRCLES					
6 Circles	EPT-C	EPTTNT-C	FPT-C		
30 Circles	EPT-C51	EPTTNT-C51	FPT-C51		
CAMO FABRIC GEL SHEET					
3 Sheets	CDG-3				
6 Sheets	CDG-6				
15 Sheets	CDG-15				
30 Sheets	CDG-30				
XERAGEL					
Gel	XSO-797			DXSO-797	TXSO-797
PRO-SIL					
Silicone	PRO-111			DRO-111	TRO-111
	PRO17-111			DRO17-111	TRO17-111
	PROK-111			DROK-111	TROK-111
PRO-SIL SPF 15					
Silicone with SPF 15	PROSP-111				
	PROSP17-111				
EPIFOAM – Gel Backed Foam Pad					
(3-pack)	EPF-3				
(Case of 30)	EPF-30				
(Case of 6)	EPF-W6				
EPIFOAM – Uncoated Foam Pad					
(3-pack)	EPFU-3				
(Case of 30)	EPFU-30				
(Case of 6)	EPFU-W6				

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Martin Mitchell, President

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