

EC Design-Examination Certificate

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

No. **CE 538130**
Issued To: **Argentum Medical LLC**
2571 Kaneville Court
Geneva
Illinois
60134
USA

In respect of:

Silverlon Antimicrobial Wound Dressings

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: **2013-06-21**

Date: **2019-10-15**

Expiry Date: **2023-06-20**

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

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
WCD-22	Silverlon Wound Contact Dressing	2" x 2"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
WCD-44		4" x 5"		
WCD-412		4" x 12"		
WCD-1012		10" x 12"		
WCD-466		4" x 66"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
DS-112	Silverlon Digit Sleeve Dressings	Tapered Digit Sleeve 1" x 12"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
WPS-112	Silverlon Wound Packing Strips	1" x 12"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
WPS-124		1" x 24"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BCD-44	Silverlon Burn Contact Dressing	4" x 5"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
BCD-48		4" x 8"		
BCD-816		8" x 16"		
BCD-1616		16" x 16"		
BCD-2424		24" x 24"		
BCD-CDL		Chest Dressing - Large		
BCD-CDM		Chest Dressing - Medium		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BWD-466	Silverlon Elastic Burn Wrap Dressing	4" x 66"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
BWD-6108		6" x 108"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ABG-01XS	Silverlon Acute Burn Glove Dressing	Extra small	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
ABG-01S		Small		
ABG-01M		Medium		
ABG-01L		Large		
ABG-01XL		X-Large		
ABG-01XXL		XX-Large		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
NPD-22	Silverlon Negative Pressure Dressing	2" x 2"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
NPD-45		4" x 5"		
NPD-58		5" x 8"		
NPD-512		5" x 12"		
NPD-1212		12" x 12"		
NPG-L		Glove - Large		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
IVCD-15	Silverlon LifeSaver Ag IV / Catheter Dressing	1" circle with 1.5mm centre hole	For the management of: <ul style="list-style-type: none"> • Vascular access (including around IV catheters, central venous lines, arterial catheters, dialysis catheters) • Drainage tube access sites • Epidural access sites • Infected wounds 	III
IVCD-40		1" circle with 4.0mm centre hole		
IVCD-70		1" circle with 7.0mm centre hole		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
WCD22-NPS	Silverlon Easy Ag Negative Pressure Dressing	2" x 2"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
WCD45-NPS		4" x 5"		
WCD58-NPS		5" x 8"		
WCD512-NPS		5" x 12"		
WCD66-NPS		6" x 6"		
WCD88-NPS		8" x 8"		
WCD1212-NPS		12" x 12"		
WCD22-NPS (-FLX)		2" x 2"		
WCD44-NPS (-FLX)		4" x 4"		
WCD48-NPS (-FLX)		4" x 8"		
WCD88-NPS (-FLX)		8" x 8"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BPD-44	Silverlon Burn Pad Dressing	4" x 5"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
BPD-48		4" x 8"		
BPD-816		8" x 16"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
WPD-22	Silverlon Wound Pad Dressing	2" x 2"	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
WPD-23		2" x 3"		
WPD-26		2" x 6"		
WPD-28		2" x 8"		
WPD-210		2" x 10"		
WPD-212		2" x 12"		
WPD-38		3" x 8"		
WPD-310		3" x 10"		
WPD-316		3" x 16"		
WPD-44		4" x 5"		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ID-23	Silverlon Adhesive Island Dressing	2.5" x 3" (1" x 1.5" pad)	For the management of: <ul style="list-style-type: none"> • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds 	III
ID-34		3" x 4" (2" x 2.5" pad)		
ID-44		4" x 4" (2" x 2" pad)		
ID-46		4" x 6" (2" x 4" pad)		
ID-410		4" x 10" (2" x 8" pad)		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
ID-412	Silverlon Adhesive Island Dressing	4" x 12" (2" x 10" pad)	For the management of: • First and second degree burns • Skin graft donor and recipient sites • Traumatic and surgical wounds • Diabetic, pressure and venous ulcers • Infected wounds	III
ID-414		4" x 14" (2" x 12" pad)		
ID-66		6" x 6" (4" x 4" pad)		

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Date	Reference Number	Action
21 June 2013	10097133 10137473	First issue.
16 June 2014	10148424	Addition of product codes WCD22-NPS (SOR), WCD44-NPS (SOR), WCD48-NPS (SOR) and WCD88-NPS (SOR).
06 March 2015	10144067	Extension of Shelf Life for Silverlon Antimicrobial Wound Dressings from 2 years to 3 years.
09 April 2015	10154770	Addition of Silverlon flex Negative Pressure Dressing to product list.
14 August 2017	8440401	Relocation of cutting process to Geneva location due to closure of Salem location. Automation of the cutting process. Closure of open commitments.

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Date	Reference Number	Action
04 May 2018	8886105	Change of critical subcontractor for silver plating process from Carolina Silver, Maiden, North Carolina to Noble Biomaterials, Scranton, Pennsylvania. DuPont™ Tyvek packaging change to transition Tyvek 1059B.
16 August 2018	8921238	Correction to typo for product codes WCD44-NPS (-FLX), WCD48-NPS (-FLX), and WCD88-NPS (-FLX) Certificate renewal.
01 March 2019	7781306	Traceable to NB 0086.
25 July 2019	9757790	Addition of ETO subcontractor International Sterilization Services Addition of new supplementary product tables Removal of product codes WCD22-NPS (SOR), WCD44-NPS (SOR), WCD48-NPS (SOR) & WCD88-NPS (SOR) Correction to dimensions for WPD-44, ID-23 & ID-34 Addition of 'Elastic' to Silverlon Burn Wrap Dressing product description & 'Ag' to Silverlon Lifesaver product description
Current	9690750	Addition of Rochester Silver Works, LLC as crucial supplier (supplier of silver nitrate)

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