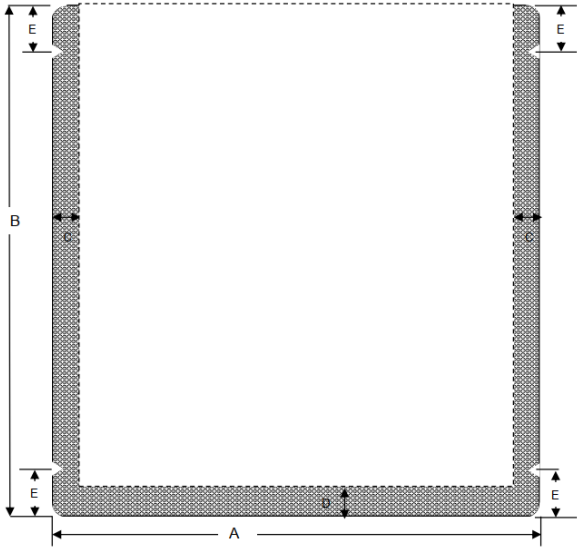
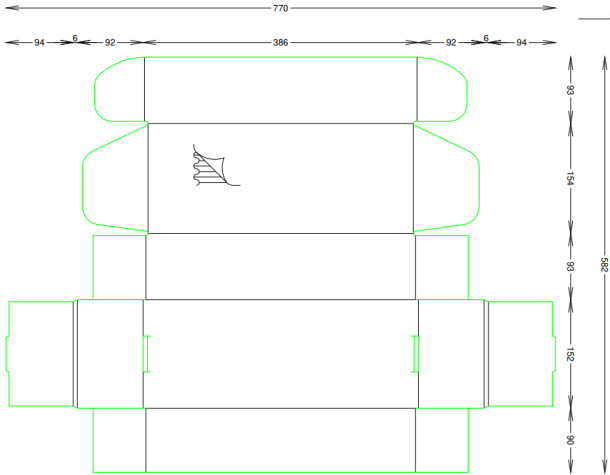




Speed Care Mineral Reference Number: CG01G/ CG01E	Name of Article: SpeedM® Emergency Hemostatic Dressing	Version 4
Intended Use:	SpeedM® is an emergency hemostatic dressing intended for temporary treatment of heavily bleeding wounds and traumatic injuries. The product is suitable for any patient to whom the intended purpose can be applied. The product is not suitable for children under 6 years of age.	
Production Specification:	<p>SpeedM®:</p> <p><u>Size:</u> 370 cm length (+/- 12 cm Tolerance) 7,5 cm width (+/- 3mm Tolerance)</p> <p><u>Fleece:</u> Spunlace Lyocell 70g/m² coarse apertured white aftertreated</p> <p><u>Weight of printing aperture at fabric:</u> 16 – 32 g/m²</p> <p><u>Number of z-folds per device:</u> 38 +/-1 Fingerlifting: first 3 folds on every side are shortend</p> <p><u>X-ray detectable strip (wave shape):</u> X-ray contrast media: BaSO₄ [Albawhite 100] Blue dye: 006P1706 NEELICERT FD & C BLUE 1</p>	
Final specification test	<p>Safety: "In vitro determination of the detachment behaviour of the mineral coating of hemostatic textile wound dressings" Test Method: <i>SOP_19 Safety1.3</i></p> <p>Performance: "In vitro measurements of the hemostatic effect Mineral-impregnated textile wound dressings" Test Method: <i>SOP_18 Performance1.3</i></p>	

Packaging Specification:

Component	Specification	Number per Product																																			
<p>Primary Packaging</p>	<p>PET/ALU/PE – 12/12/75 µm</p> <p>Gruber Folien, Germany</p>	 <p>Technical drawing of primary product packaging</p> <table border="1" data-bbox="724 1137 1382 1279"> <thead> <tr> <th></th> <th></th> <th></th> <th></th> <th>Toleranz / tolerance</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>Beutelbreite / width</td> <td>140</td> <td>mm</td> <td>± 5 mm</td> </tr> <tr> <td>B</td> <td>Beutellänge / length</td> <td>130</td> <td>mm</td> <td>± 5 mm</td> </tr> <tr> <td>C</td> <td>Seitennaht / side seam</td> <td>10</td> <td>mm</td> <td>± 2 mm</td> </tr> <tr> <td>D</td> <td>Bodennaht / bottom seam</td> <td>10</td> <td>mm</td> <td>± 2 mm</td> </tr> <tr> <td>E</td> <td>Position Einreißkerben / position tear notch</td> <td>35</td> <td>mm</td> <td>± 2 mm</td> </tr> <tr> <td>Verbundfolie / composite film</td> <td>PET/ALU/PE – 12/12/75</td> <td>99</td> <td>µm</td> <td>± 10 %</td> </tr> </tbody> </table>					Toleranz / tolerance	A	Beutelbreite / width	140	mm	± 5 mm	B	Beutellänge / length	130	mm	± 5 mm	C	Seitennaht / side seam	10	mm	± 2 mm	D	Bodennaht / bottom seam	10	mm	± 2 mm	E	Position Einreißkerben / position tear notch	35	mm	± 2 mm	Verbundfolie / composite film	PET/ALU/PE – 12/12/75	99	µm	± 10 %
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<p>Secondary Packaging</p> <p>Containing 15 finished primary packaged products each upright</p> <p>Each dispenser box contains:</p> <ul style="list-style-type: none"> - 1 IFU in the respective language - 5 questionnaires in the respective language 	<p>Dispenser box</p> <p>Inner dimension 368x150x91 mm</p> <p>Grade thickness: 1.5 mm</p> <p>Weight: 0.182 kg p/piece / +/- 10%</p> <p>Packners, Germany</p>																																				

		
<p>Tertiary Packaging</p> <p>Containing 12 secondary packaging dispenser boxes each</p>	<p>Shipping Box</p> <p>Inner dimension 585x385x316 mm</p> <p>Grade thickness: 5.6 mm</p> <p>Weight: 0.922 kg p/piece / +/- 10%</p> <p>Packners, Germany</p>	

Labeling Specification:

<p>Primary Packaging Label</p>	<p>English Version</p>	
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Secondary Packaging Label

English Version
SCM2024015
Rev00 Etikett
Spender



Speed Care Mineral GmbH
Genzkower Straße 7
DE-17034, Neubrandenburg
Tel.: +49 395 423920
Fax: +49 395 4239227
email: info@speedcaremineral.de
Internet: www.speedcaremineral.de

REF CG01E

SpeedM® **Emergency Hemostatic Dressing**

Content: 15 pieces

LOT JJMMXXXX JJJJ-MM JJJJ-MM-TT



STERILE R



Made in Germany



SCM2024015 Rev00 10/2024

Tertiary Packaging Label

English Version
SCM2024016
Rev00 Etikett
Umkarton



Speed Care Mineral GmbH
Genzkower Straße 7
DE-17034, Neubrandenburg
Tel.: +49 395 423920
Fax: +49 395 4239227
email: info@speedcaremineral.de
Internet: www.speedcaremineral.de

REF CG01E

SpeedM® **Emergency Hemostatic Dressing**

Content: 12 dispenser boxes of 15 pieces

LOT 1 2024-10 2028-08-14



STERILE R




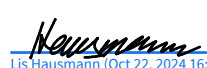
Made in Germany



SCM2024016 Rev00 10/2024

Instruction for Use:

Instructions for use SpeedM Emergency Hemostatic Dressing
SCM2024012 Rev00 IFU SpeedM Eng

Shelf Life:	5 years	
Storage conditions:	< 25°C	
Sterilisation:	<p>Gamma Irradiation, BGS Beta-Gamma-Service GmbH & Co. KG, John-Deere-Straße 1, 76646 Bruchsal, Germany</p> <p>Dose limit: Minimum 25.00 kGy, Maximum 50.00 kGy Triple Dose Mapping Validation of sterilization acc. To VD_{max}²⁵</p> <p><i>Technical report 056071-0-1-237650-B_signed_KORR</i></p>	
Release Parameter:	<p>Defined in: <i>FB 05.04.01.02 Rev04 Phasenfreigabe Produktion</i></p> <ul style="list-style-type: none"> - Certificate of analysis HNT - Quality test certificate Compound - Test certificate barium sulfate - CoA Blue color - Certificate of Analysis Norafin - Test certificate printing / cutting - Certificate of Analysis Safety and Performance testing - Certificate of Compliance Finishing Folding / Packing - Certificate of Analysis Sterilization 	
Signatures		
22.10.2024		22/10/24  <small>Lis Hausmann (Oct 22, 2024 16:26 GMT+2)</small>
Prepared Qualitätsmanagement Kerstin Lindae	Approved Manager Regulatory Affairs Lis Hausmann	

Shipment documentation:

Attachments:

SOP_19 Safety1.3
SOP_18 Performance1.3
SCM2024015 Rev00 Etikett Spender
SCM2024016 Rev00 Etikett Umkarton
SCM2024012 Rev00 IFU SpeedM Eng
Technical report 056071-0-1-237650-B_signed_KORR
FB 05.04.01.02 Rev04 Phasenfreigabe Produktion






Final Product Specification V5 2024-10-22

Final Audit Report

2024-10-22

Created:	2024-10-22
By:	Kerstin Lindae (kl@speedcaremineral.com)
Status:	Signed
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