



**STERILE IMPREGNATED DRESSINGS FOR BURNS
 STERILE BANDAGES FOR BURNS**

Flamaderm

Technical specifications

No.: 03/01.1

Description			
Name	References	Final dimensions	UDI-DI
Sterile impregnated dressings for burns	3.100GM	10 cm x 10 cm	5944729006798
	3.410GM	10 cm x 40 cm	5944729006804
	3.200GM	20 cm x 20 cm	5944729006835
	3.420GM	20 cm x 40 cm	5944729006842
	3.M245GM	20 cm x 45 cm Child Facial Mask	5944729006880
	3.255GM	20 cm x 55 cm with finger cutouts	5944729006859
	3.400GM	40 cm x 40 cm	5944729006910
	3.640GM	40 cm x 60 cm	5944729006811
	3.M640GM	40 cm x 60 cm Facial Mask	5944729006866
	3.800GM	80 cm x 80 cm	5944729006873
	3.1612GM	100 cm x 200 cm	5944729006828
	3.1518GM	120 cm x 160 cm	5944729006903
Sterile bandages for burns	3DGM	2.5 cm x 50 cm Finger	5944729006989
	3MGM	5 cm x 100 cm Hand	5944729006972
	3.107GM	7 cm x 100 cm	5944729006996
Composition			
<ul style="list-style-type: none"> Support made of alveolar polyurethane (foam) Impregnation: hydrogel, in excess Hydrogel: Carbopol, Glycerin, Propylene glycol, Sodium hydroxide 10%, Menthol 0.05%, Purified water 			



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pH
5.5 – 7.5
Odor
Characteristic of menthol
Sterilized by:
Radiation
Shelf life:
5 years
Packaging
Envelopes made of aluminized foil
Regulatory status
IIb Class medical device according to Directive 93/42/EEC
Applicable standards
EN ISO 13485; EN ISO 10993-1; EN ISO 10993-3; EN ISO 10993-5; EN ISO 10993-10; EN ISO 10993-11; EN ISO 10993-18; EN ISO 10993-19; EN ISO 10993-23; EN ISO 14971; EN ISO 15223-1; EN ISO 20417; EN 62366-1; EN ISO 11137-2; EN ISO 11737-1; EN ISO 11737-2; EN ISO 11607-1; EN ISO 11607-2
Storage
Store in a dry place at temperature lower than 35 ⁰ C and protect from sunlight and humidity
Disposal considerations
Disposal of in accordance with all national, territorial and European regulation. The products should not be discharged to the environment.
Intended use
Products are used in first aid in case of burns, including sunburns and chemical burns, I, II and III degree.

Packaging

Carton box.

No. of pcs/box: as required.

Sterilization

- Products are sterilized by gamma radiation, based on a sterilization process validated according to EN ISO 11137