

MELAfol[®] • See-through sterilization package according to EN 868-5

Manufacturer / Supplier: MELAG Medical Technology, Geneststraße 6 - 10, D - 10829 Berlin

Product description

MELAfol[®] is a prefabricated sterile barrier system according to ISO 11607-1, with chevron-sealing seam. It consists of a germ-proof, heat sealable paper and plastic composite foil. MELAfol[®] is available in rolls, as individual bags or as bags with gusset.

Application area

MELAfol[®] is appropriate for packaging various items to be sterilized (instruments, trays, towels, sets, etc.) for long-term contamination-protected storage of sterilized materials.

Method of sterilization

Suitable for steam-, ethylene oxide- and formaldehyde sterilization

► (MELAfol[®] See-through sterilization package is not suitable for plasma and gamma irradiation and as well hot-air sterilization.)

Sealing temperature

Recommended sealing temperature: 170 – 185° C / 338 – 365° F (standard values)

Features

- Impermeable to bacteria
- Heat sealable
- Crease-resistance and excellent peel ability by “peelable sealing seams“, these enable a quick and clean opening without release of fibers or contaminated particles.
- Steam sterilization indicator, according to ISO 11140-1 – Treatment indicator that turns from pink to brown during the sterilization
- (This indicator shows whether the product has been sterilized. It does not show whether the sterilization was successful or not.)

Storage conditions

The products should be stored in horizontal position, in dry and cool conditions and protect from direct sunlight.

- Storage temperature: 10 - 30 °C / 50 – 86° F
- Relative air humidity: 30 - 60 %

The appropriately stored products may be used for 5 years from date of manufacture (see packaging).

Tests and approvals

MELAfol[®] complies with the following standards and guidelines:

- Guideline for medical devices 93/42/EG Annex I
- DIN EN ISO 11607-1
- Heat sealable according to DIN EN 868-5;
- Sterilized material in see-through sterilization package is storable for up to 6 month after the sterilization in a protected environment (dust free), according to DIN 58953-8
- MELAfol[®] See-through sterilization package have an indicator that turns from pink to brown during the sterilization, according to DIN 58953- 4

Product data

See-through sterilization package on a roll

MELAfol® 502	5 cm x 200 m
MELAfol® 752	7,5 cm x 200 m
MELAfol® 1002	10 cm x 200 m
MELAfol® 1502	15 cm x 200 m
MELAfol® 2002	20 cm x 200 m
MELAfol® 2502	25 cm x 200 m

See-through sterilization package – packing unit 1000 pieces

MELAfol® 501	5 x 25 cm
MELAfol® 751	7,5 x 25 cm
MELAfol® 1001	10 x 25 cm

See-through sterilization package – packing unit 100 pieces

MELAfol® 2051* (with gusset)	20 x 50 cm
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* for sealing standard-try-cassettes

Technical Data

Paper:

High-quality features	UNIT	STANDARDS	TYPIC	MIN	MAX
Substance	g/m ²	ISO 536	60	57	63
Mechanical strength MD	kN/m	EN ISO 1924-2	6,30	4,67	
Mechanical strength CD	kN/m	EN ISO 1924-2	3,30	2,33	
Mechanical strength after sterilization MD	kN/m	ISO 3781	2,00	0,90	
Mechanical strength after sterilization CD	kN/m	ISO 3781	1,1	0,5	
Burst strength	kPa	ISO 2758	350	230	
Burst strength after sterilization	kPa	ISO 3689	130	70	
Tensile strength MD	mN	EN 21974	600	550	
Tensile strength CD	mN	EN 21974	650	550	
Porosity / Roughness (Bendtsen)	ml/mn	ISO 5636-3	1000	800	1250
Hydrophobia	s	EN 868-3 (Appendix A)	35	20	
Cobb-Test (60 s) (absorbance value)	g/m ²	EN 20535	15		20
Aqueous extract – PH-Value		ISO 6588	7	5	8
Sulfate	%	ISO 9198			0,25
Chloride	%	ISO 9197-1			0,05
Pores	µm	EN 868-3 (Appendix B)	21		35
Fluorescence	%	DIN 58953-6	0		

Lamination:

PROPERTIES	UNIT	STANDARDS	VALUES
Polyester	g/m ²	SPS	16 to 17,4
Polyester: strength	µm	SPS	12 +/-5%
Adhesive	g/m ²	SPS	1,65 +/- 0,15
Polypropylene	g/m ²	SPS	32,5 to 35,9
Polypropylene: strength	µm	SPS	36 to 40

Pouches and tubes:

PROPERTIES	UNIT	STANDARDS	VALUES
Seal strength	N/15 mm	EN 868	≥ 1,5