



LAUFENBERG

RELEASE LINER



SILICONE COATED PAPERS AND FILMS

DEDICATED TO MEDICAL APPLICATIONS

Laufenberg is a specialist for the development and manufacturing of single and double side silicone coated papers and films, so called release liners.

We have been supplying products for the medical sector for more than 50 years, used for the manufacturing of simple to special medical applications. These include, amongst others, (transdermal) wound dressings, self-adhesive electrodes and components for ostomy products.

As the adhesive used in medical products is in direct skin contact, a consistent and high quality standard is essential to ensure a safe and easy product application for the end user.



MEDICAL LINER | PRODUCTION STANDARD

Laufenberg medical release liners are used in highly developed applications. In order to meet the requirements of our customers, we run our production on a high level of cleanliness. Our own quality and safety requirements are based on five ISO certifications. The following systems are installed by default.

- Transponder-secured access authorization
- Hygiene concept
- FOD-Program (Foreign Object Debris)
- 5S method
- Double door system
- Air filters in the production halls
- Pest control program
- Zero failure strategy
- Continuous internal auditing
- Optical web inspection systems
- Special & controlled working conditions & environment for medical production runs

	APPLICATION	CARRIER
	Diagnostics	Polyester
	Clinic supplies	Polyester, Glassine
	Wound dressings, transdermal wound dressings	Polyester, Aluminized Polyester, Glassine, Poly coated kraft
	Hydrophylic foam	Poly coated kraft
	Stoma care	Polyester, Glassine, Poly coated kraft



HIGH-QUALITY | CERTIFIED | DEMAND-DRIVEN

Our advantages

- 65 years of experience in the field of siliconized liners, 50 years of it in medical applications
- Wide product portfolio of papers and films
- Roll finishing from 12 - 2350mm/ ½ " - 92,5 "
- Optical web inspection system
- Low MOQ (minimum order quantity) from 10,000 m²
- Remoistening up to 7% possible
- Conformity certificates according to BfR/FDA
- DMF registration for selected products
- IMS: Various certifications / validations
- Own laboratory with extensive analytical equipment
- Permanent monitoring and auditing of suppliers
- Support of the sterilization process of our customers by special precautions in our production, with which the germ content is reduced



Our additional services

- Compliance Management
- External testing upon request, e.g. bioburden test
- Double bagging for clean room production
- Plastic cores for a wide range of roll widths
- All MED-release liners are available with a wide range of release levels from easy to very tight
- Long-term support through all qualification phases



Our IMS combines the different management systems of Laufenberg, connects them in a unified way and controls the associated processes.



PE COATED PAPERS | ONE OR TWO-SIDED COATING

	BfR III	BfR XXXVI	FDA §175.300	FDA §176.170	FDA §176.180	FDA §177.1520	DMF (Coating)
NP 750 MED white	✓	✓	✓	✓	✓	✓	✓
NP 950 MED white	✓	✓	✓	✓	✓	✓	✓
NP 1100 MED white	✓	✓	✓	✓	✓	✓	✓
NP 1200 MED white	✓	✓	✓	✓	✓	✓	✓
In relation to	Polyethylene	Paper	Polymers as coating	Papers for humid or greasy food	Paper for dry food	Polyethylene	Drug Master File Silicone and coating process





POLYESTER FILMS | ONE OR TWO-SIDED COATING

	BfR XV	BfR XVII	VO 10/2011	FDA §175.300	FDA §177.1630	DMF (Coating)	DMF (Base)
PETP 36µm MED transparent		✓	✓	✓	✓	✓	
PETP 50µm MED transparent		✓	✓	✓	✓	✓	
PETP 75µm MED transparent			✓	✓	✓	✓	
PETP 100µm MED transparent			✓	✓	✓	✓	
PETP 125µm MED transparent			✓	✓		✓	
PETP 36µm MED transparent DMF		✓	✓	✓	✓	✓	✓
PETP 50µm MED transparent DMF		✓	✓	✓	✓	✓	✓
PETP 75µm MED transparent DMF		✓	✓	✓	✓	✓	✓
PETP 100µm MED transparent DMF		✓	✓	✓	✓	✓	✓
PETP/B 36µm MED transparent	✓		✓	✓	✓	✓	
PETP/B 50µm MED transparent	✓		✓	✓	✓	✓	
PETP/B 75µm MED transparent	✓		✓	✓	✓	✓	
In relation to	Silicone	Non siliconized Polyesterfilm	Non siliconized Polyesterfilm	Polymers as coating	Non siliconized Polyesterfilm	Drug Master File Silicone & Coating Process	Drug Master File Base Material



GLASSINE PAPERS | ONE OR TWO-SIDED COATING

	BfR XV	BfR XXXVI	FDA §175.300	FDA §176.170	FDA §176.180	DMF (Coating)
B 400 MED white	✓	✓	✓		✓	✓
L 650 MED white	✓	✓	✓	✓	✓	✓
L 650 MED light yellow	✓	✓	✓	✓	✓	✓
B 650 MED white	✓	✓	✓	✓	✓	✓
B 650 MED light yellow	✓	✓	✓	✓	✓	✓
KS 800 MED white	✓	✓	✓	✓	✓	✓
KS 900 MED white	✓	✓	✓	✓	✓	✓
KS 1200 MED white	✓	✓	✓	✓	✓	✓
KS 1400 MED white	✓	✓	✓	✓	✓	✓
In relation to	Silicone	Paper	Polymers as coating	Papers for humid or greasy food	Paper for dry food	Drug Master File Silicone and coating process

The raw materials used comply with the specified guidelines. Our finished products have not been tested for compliance. It is basically the responsibility of the "person placing the product on the market" to check whether there are any restrictions for contact with food/applications in medical use.



Risiken erkennen – Gesundheit schützen

The Federal agency for risk assessment (Bundesanstalt für Risikobewertung) is responsible for scientific counseling to the federal government in terms of food safety, product safety, contamination in the food chain, animal welfare and sanitary consumer protection. With this work the institute should make a contribution to the health of consumers by making food, substances and products safer. So called “recommendations” are originated out of this.



equipment that emits radiation. This is valid for products manufactured in the USA, as well as for imported products.

The Food and Drug Administration is the regulatory food inspection and pharmaceutical admission office of the United States of America. Their responsibility is to ensure the safety of public health in the USA. The FDA controls the safety and effectiveness of medication used in human and veterinary medicine, biological products, medical products, food, and

DMF

A Drug Master File is a document where the pharmaceutical production and quality assurance of a drug is documented against a drug administration regulation for certification purposes. In our DMF's 10968, B20200001228 and B20190002119, we provide information to the American Authority as well as the Chinese Authority about our product regarding components used and manufacturing processes. Our customers refer to this DMF, where the Authority then has all necessary information available about our product.



WE CARE | SUSTAINABILITY AT LAUFENBERG

Laufenberg pursues a holistic sustainability strategy. We strive to maintain a meaningful balance between economic development, environmental responsibility and social equity and to promote and implement all three sustainability dimensions in and with our company.

In numerous projects, we have dedicated ourselves for many years to sustainable developments and the responsible use of finite resources. The aim is generation-fair and environmentally friendly corporate development, including the development of energy-saving and sustainable products.



QUESTIONS? GET IN TOUCH -
WE LOOK FORWARD TO TALK TO YOU!

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