RENOLIT SOLMED.
Don’t compromise when it comes to human lives.

The complete range of medical grade plastics
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**RENOILIT MEDICAL**

The RENOLIT Group is the world’s leading producer of medical grade semi-finished plastic products. The Business Unit RENOLIT MEDICAL is specialized in medical grade plastics: PVC, PP, PE, EVA and custom made formulations. Sold under the name RENOLIT SOLMED these products have been used for more than 40 years by the world’s leading medical device manufacturers and pharmaceutical companies.

The RENOLIT SOLMED medical grade plastics offer manufacturers of the final products in all sectors of the medical and pharmaceutical industry the highest reliability and unsurpassed functionality. RENOLIT SOLMED formulations comply with international standards, such as ISO 10993 and 3826, European Pharmacopeia, United States Pharmacopeia, Japanese Pharmacopeia and Chinese Pharmacopeia. The superior quality and consistency ensures optimal machineability on high speed automated production lines. This proven reliability results in high production efficiency.

Our worldwide organization offers a high level of technical support, research and co-development, including co-design. Full registration support and master files are available. The vast experience of over 40 years, and the specialized knowledge of production techniques and properties of medical grade materials, are a solid background for the world wide support to our customers.

We know a human life can depend on the quality of our materials. We feel as responsible as you do. Because our basic materials are used for the production of life-saving medical devices, we are committed to manufacturing the highest possible quality. Our goal is to comply with all our customers’ specifications and to meet the strictest requirements for medical applications. Reliability, innovation and partnership are what we stand for. RENOLIT SOLMED - medical grade plastics you can rely on.

**YOUR GLOBAL PARTNER FOR QUALITY YOU CAN RELY ON.**

The RENOLIT Group is a leading global specialist for high-quality plastic films, sheets and other plastic products. With more than thirty production sites and sales entities in over twenty countries, the company is one of the world’s leading plastic product manufacturers. Today more than 4,700 employees continue to further the knowledge and expertise gained from over seventy years of business. Always developed with our customer requirements in mind and manufactured to the highest quality, our products can often make a vital difference.
RENOLIT is known as the worldwide market leader for the basic materials for the manufacturing of blood bag systems. RENOLIT SOLMED Transfufol, Infufol and ES blood bag films are supplied to the world’s leading manufacturers of blood bags and blood processing systems such as aphaeresis and therapeutic treatments. Important factors are the consistent and reliable quality of the films, often custom made in co-development with our customers.

Some features are: Superior embossing stability during the 121°C steam sterilization procedure, guaranteeing the non-blocking properties on both sides of the film. Different surface structures are available enabling good blood separation both on automatic as well as semi-automatic fractionation machines.

The compositions of RENOLIT SOLMED blood bag films have been carefully tested for their blood compatibility. Various formulations are available, including DEHP, TEHTM, DINCH and citrate plasticized films. Special PVC and polyolefin compounds offer high oxygen and carbon dioxide permeability for platelet storage as well as for frozen and cryogenic storage. Thickness ranges from 0.20 to 0.75 mm, width ranges from 50 to 1350 mm (film type depending).

The specially developed RENOLIT SOLMED Transfufol film processing technique combines the advantages of calendaring and extrusion, resulting in a superior batch-to-batch consistency. The strict clean room conditions, web cleaning technology and in-line cutting guarantee a low particulate level.

The packaging of blood and blood components is known as one of the most critical applications, the developments are frequent and the requirements are increasing every day.
Today, flexible plastic single use systems are replacing traditional glass and stainless steel in applications like media storage bags, bioreactors, mixing vessels, product storage and sampling containers. These disposable pre-sterilized systems are increasingly considered a safer and less costly alternative to stainless steel equipment. This trend in the biotechnology industry is supported by exciting new developments in the plastic components of such flexible disposable systems. These components have to fulfill the severe and strict product properties that are required for critical biotechnology and pharmaceutical applications.

In this field, RENOLIT SOLMED is one of the leading suppliers of packaging materials for the most critical applications. After the introduction in the 1990's of the EVA based BF film range suitable for 2D and 3D bag design we have introduced the new generation of PE based Biotech films.

The new RENOLIT SOLMED Infuflex Barrier films comprise ultra pure inert PE inner and outer layers and an oxygen barrier layer. The high barrier properties of these films offer significant advantages in the storage of oxygen sensitive products. The film exhibits extremely low extractables, excellent high clarity and is resistant to a wide range of chemicals. The unique film structure combined with a 1400 mm film width offers excellent weld strength in both 2D and 3D bag designs which are now the new standard in the biotechnology industry. The raw materials in these films have been carefully selected. Coupled with our multi-continent film production sites, this builds a robust supply chain and ensures long term availability. In addition, RENOLIT SOLMED Infuflex Barrier films are produced under strict controls to minimize the risk for particulates.

RENOLIT SOLMED Medipak UVD offers excellent oxygen, carbon dioxide and UV barrier properties. Available in widths of 125 to 400 mm, this 5 layer coextruded tubular film is suitable for media bags up to 20 liter capacity.

Special EVA and polyolefin films are available for stem cell storage and cell culturing applications. These specially developed materials combine very high oxygen and carbon dioxide transmission rates with excellent cold storage properties down to -196˚C (liquid nitrogen, cryogenic). Special tubing types are available for fluid transportation.

For the assembly of biotechnology systems RENOLIT offers a highly flexible Shore-A 60 tubing. The special TPE based formulation has been developed for pharmaceutical fluid transfer in biotechnology systems including media, buffer solutions and the pharmaceutical products and intermediates.

The RENOLIT SOLMED Tubeflex fluid transfer tubing has been extensively tested for chemical and biocompatibility properties according to various Pharmacopoeia and the ISO 10993 standard. In addition an extractables/leachables study has been performed confirming the ultra pure nature of the tubing. The pump performance exceeds that of the traditional elastomer tubing types.

Special EVA and polyolefin films, exhibiting excellent cold storage behavior, are available for stem cell storage.
Dialysis

For Renal Intensive Care Treatments, multi-compartment polypropylene bags with peelable seal or special high pH resistant PVC bags are used to store sterile solutions based on sodium bicarbonate. Such bags are also used for highly concentrated dialysis solutions.

All these specialty bags can be manufactured from a range of RENOLIT SOLMED films, depending on the customer's choice:

- RENOLIT SOLMED Medipak: tubular PVC film for sterile solution packaging
- RENOLIT SOLMED Medipak Alka: tubular PVC film for the packaging of sterile sodium bicarbonate solutions and other solutions with a pH > 7
- RENOLIT SOLMED Infiltex: polyolefin film, flexible and transparent. Suitable for multi-chamber bags with peelable seal technology
- RENOLIT SOLMED Tubeflex: polyolefin tubing for use with RENOLIT SOLMED Mediflex and Infiltex

The applications of RENOLIT SOLMED products in peritoneal dialysis are highly diverse.

In peritoneal dialysis treatments, the peritoneal cavity of the patient is being used to act as dialyzing membrane. Usually being applied as a home therapy, the patient can enjoy a relatively high freedom of movement without the need for frequent visits to the clinic or hospital.

DIALYSIS

One of the largest application areas for RENOLIT SOLMED products is dialysis. Developments are progressing quickly and there is a large diversity in the various types of haemodialysis and peritoneal dialysis applications. RENOLIT SOLMED materials play an important role in virtually all possible dialysis related systems and devices. Together with partners we work on the development of the next generation of dialysis systems.

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RENOlit provides the double bag CAPD system ready to fill using PVC or PP material and the individual components.

RENOlit SOLMED materials are suitable for the traditional lactate based CAPD solutions and also for the next generation sodium bicarbonate solutions with pH > 7 and specialty glucose or amino acids solutions. Special drainage bags are available in PVC and polyolefin material suitable for CAPD systems as well as for automated PD applications. The high quality of RENOLIT SOLMED products will help ensure reliable dialysis systems.

For haemodialysis treatment, the patient has to visit the clinic several times per week. For connecting to the dialysis machine, advanced tubing systems or “Blood Lines” are made from RENOLIT SOLMED Medituub. Special RENOLIT SOLMED Medituub grades are available for steam sterilized haemodialysis tubing sets. The specially developed non-blocking and non-kinking properties ensure reliable and trouble-free use.
IV AND PHARMACOLOGICAL APPLICATIONS

The use of flexible bags for IV applications offers significant advantages over the traditional glass bottles and blown plastic containers. One of the most important aspects is the collapsibility of a flexible bag, making air vents redundant. Other benefits include weight and volume reduction and high transparency. Today the decisive factors in IV applications are quality, reliability and cost. RENOLIT SOLMED sets the standard in all aspects.

RENOLIT offers a complete system for the manufacture of reliable and high quality IV bags, both in PVC and in polyolefin materials:

- RENOLIT SOLMED Medipak (PVC) and Mediflex (PP) tubular film; Infuflex and MF doublewound PP flat film
- RENOLIT SOLMED Medistub (PVC) and Tubeflex (PP); monolayer for PP ports and multilayer PP or PP/PVC for PC ports
- RENOLIT SOLMED Medigranul (PVC) and Granuflex (PP) injection molding compounds for port manufacturing
- RENOLIT SOLMED ports and caps for IV bags and plastic bottles

The storage of drugs, active ingredients or other pharmaceutical solutions is supported by a wide range of film and tubing compositions.

RENOLIT SOLMED Medipak and Mediflex are the standard for the packaging of sterile IV and pharmaceutical solutions. These PVC and polyolefin (PP) based tubular films have proven to be the most reliable and cost effective material for IV bags. Due to its closed system, the interior of the tubular film is virtually free of particulate contamination, microorganisms and pyrogens. A major advantage of the tubular film is the number of welds, reduced to an absolute minimum, thereby increasing the reliability of the final device. Another important advantage of tubular film is the cost saving effect of reducing film waste during the production of bags.

RENOLIT SOLMED Infuflex and MF polyolefin based flat films are supplied either double wound or single wound for use on high speed automated form fill seal equipment. The RENOLIT SOLMED film compositions have been tested according to the relevant ISO 10993 standards and fulfill the test requirements of the various pharmacopoeia.

For polyolefin IV systems the unique RENOLIT SOLMED monolayer Tubeflex types, combined with PP based RENOLIT SOLMED Granuflex injection molded ports, offer a significant economic advantage compared with the multilayer RENOLIT SOLMED Tubeflex used for polycarbonate ports. A combination of coextruded PP/PVC tubing is possible as well.

For IV administration sets, RENOLIT SOLMED Medistub is the material of choice. Main features are the superior non-kinking properties, excellent transparency and high suitability for steam, ETO and gamma sterilization. For critical applications, the coextruded RENOLIT SOLMED Medistub 3-layer PVC/PE tubing avoids drug ab-/adsorption to the tubing wall.

RENOLIT offers a complete range of PVC and polyolefin material for the manufacture of reliable and high quality IV bags.

The storage of IV solutions, drugs, active ingredients or other pharmaceutical solutions is supported by a wide range of film and tubing compositions.
PORTS AND CAPS

The production of flexible bags or plastic bottles for intravenous solutions requires specially designed ports and caps. The RENOLIT SOLMED product range offers a large variety of high quality components for use on automated form fill seal and blow fill seal machines.

For flexible bags for intravenous solutions we propose polypropylene port and cap systems that can be sealed directly to the film. Bags with flexible tubing can be fitted with polycarbonate spike ports and injection ports as well as with polypropylene twist-off ports.

The design and rubber composition of the polycarbonate spike ports and injection ports offer excellent spike retention and assure a minimum fragmentation upon piercing.

RENOLIT’s unique port and cap designs support a highly cost effective and automated flexible bag manufacturing.

A range of high quality caps is available for the manufacturing of blow molded plastic bottles for IV solutions including Eurohead caps and more. These caps can be supplied in polypropylene and polyethylene compositions to assure compatibility with the bottle material and with the sterilization temperature; up to 121 °C for polypropylene caps.

The RENOLIT ports and caps are manufactured on automated injection molding machines and assembled in class 7 clean rooms.

General note: Certain ports and caps may not be available for sale in all countries.
Nutrition

The requirements for the packaging of sterile parenteral nutrition solutions depend largely on the type of solution, sterilization method and specific barrier properties required. RENOLIT SOLMED PP and EVA are used for the storage of lyophilic solutions; an application where PVC with Tehtm or DINCH plasticizers are also used.

RENOLIT SOLMED Medipak EVA tubular film is available in a clear, frosted surface and a ribbed version. A special surface embossing on the outside of the tubular film reduces the sticking and blocking effect, and facilitates its use on automated welding machines. RENOLIT SOLMED EVA flat film is available in a combination of transparent and frosted surface.

Parenteral nutrition solutions containing amino acids and vitamins require high barriers to oxygen and UV light. Several multilayer RENOLIT SOLMED films offer these barrier functions and excellent cold temperature resistance. The coextruded RENOLIT SOLMED Medipak UVO tubular film contains an EVA fluid contact layer, is high frequency weldable and the film is suitable for ETO and gamma sterilization.

Special RENOLIT SOLMED Meditub EVA and coextruded PVC/EVA Meditub are available to ensure a proper connection with the bag ports.

Many parenteral nutrition solutions are steam sterilized at 121°C and contain components, such as glucose and amino acids, which must be stored separately. These applications require steam sterilizable multicompartment bags with peelable seal, which can be manufactured from the RENOLIT SOLMED Infuflex polyolefin films. In combination with RENOLIT SOLMED Tubeflex tubing and RENOLIT SOLMED Granuflex based ports, a complete polyolefin system can be realized.

The RENOLIT SOLMED Infuflex product range also offers a unique high oxygen barrier film suitable for multi-compartment bags with peelable seal. This innovative barrier film keeps its high clarity and flexibility after steam sterilization at 121°C.

The high barrier properties of this film offer significant advantages in the storage of oxygen sensitive products such as amino acids and lipids, reducing or eliminating the need for a barrier overwrap package and oxygen scavengers.

Enteral nutrition applications require reliable and cost effective packaging materials. Various RENOLIT SOLMED materials are available for the large diversity in enteral feeding products:

- RENOLIT SOLMED Transfuful extruded film
- RENOLIT SOLCARE calendered films cost effective and available in clear and white
- RENOLIT SOLMED EVA flat film and RENOLIT SOLMED Medipak EVA tubular film, often used for longer shelf-life storage of fatty solutions

Many nutrition solutions require steam sterilizable, oxygen barrier multicompartment bags with peelable seal.
Laminated films for the manufacturing of solution bags and overwraps with high barrier properties; co-extruded multi-layer polyolefin films for the overwrapping of sterile solution bags, blood bag systems and medical devices.

RENOLIT SOLMED Renoguard laminated films are produced under clean room conditions. Main applications include packaging of pharmaceutical solutions and materials, e.g. as primary or overwrap barrier film. For sensitive pharmaceutical solutions we offer high clarity RENOLIT SOLMED Renoguard films with oxygen and carbon dioxide barrier properties. All RENOLIT SOLMED Renoguard structures have a base polyolefin layer laminated with different layers to obtain special functions and properties like barriers, heat shield, drop resistance and more. Production of the base film as well as the laminating step takes place under clean room conditions.

Various types of barrier films include PET-AlOx, PET-SiOx and others. The film structures allow for peelable or permanent seal. Processing of the films can be done either on automated pouch-making, manual welding or flowpack equipment. RENOLIT SOLMED Renoguard are tested for biocompatibility and cytotoxicity and conform with European Food Legislation.

SECONDARY PACKAGING

RENOULIT SOLMED Wrapflex films are manufactured from medical grade raw materials in a clean room. The system is based on a reliable peelable seal opening of the overwrap package with proven functionality for a.o. IV bags and blood bag systems. The films can easily be processed on all modern overwrapping machines. The bottom film can be thermoformed to offer a perfect fit around the product.

PACKAGING OF DRY MEDICAL DEVICES

RENOULIT SOLMED Carepack thermoformable films have been developed for the packaging of dry medical devices, such as bandages, catheters or operation gowns. These films can be sterilized by means of ETO, irradiation or steam sterilization.

RENOULIT SOLMED Carepack films are produced in a clean room. Suitable substrates include medical grade paper and polymer based substrates. Significant cost saving can be achieved when combining RENOLIT SOLMED Carepack films with uncoated paper or uncoated spunbonded PE based substrates.

FOOD AND NUTRITION PACKAGING

RENOULIT SOLMED Renoprop/Renopeel retortable converter films for food and nutrition packaging offer high (peel-) seal strength, have best mechanical properties, are free from additives and have high flexibility and transparency. Due to their full PP composition, they offer an excellent price/performance ratio. These films are manufactured under certified BRC-IOp conditions in a clean room. Processing of these films is by printing, lamination, thermoforming and sealing.

Blood bag sets can be packed and steam sterilized in RENOLIT SOLMED Wrapflex films.
Strict procedures for Quality Assurance and Quality Control are used and many additional precautions are taken to ensure a clean and compliant production environment.

- HEPA filtered air
- positive pressure
- specially validated clean room sections for critical products
- clean room clothing, hair and beard covers, special shoes
- insulated machine area
- restricted entry
- regular audits

The operators are trained regularly regarding quality procedures and essential GMP subjects.

The production equipment is custom made and specially designed to operate in a controlled environment.

All products are packed in double polyethylene bags before leaving the production clean room. In a special packaging area, the products are packaged according to customer specifications and shipped to the warehouse. The packaging is developed to minimize the risk of transport damage. Multi-roll carton boxes reduce the amount of packaging materials without compromising the packaging’s integrity. For long distance intercontinental shipments a specially developed packing system is used to protect the product and to optimize container loads.
This implies that the maximum obtainable quality level of the final product is significantly influenced by the RENOLIT production phase. Our commitment therefore is to manufacture the best possible quality according to the specifications and requirements of our customers.

RENOLIT SOLMED quality system of our plants is ISO 13485 or ISO 9001 certified to meet the pharmaceutical and medical device industry requirements. The quality system for the complementary production sites is ISO 9001 certified.

RENOLIT SOLMED products have been developed in accordance with various international Pharmacopoeias in order to meet the strictest requirements for medical applications.

The RENOLIT SOLMED products are based on a unique and sensitive balance between choice of raw material, composition and processing conditions. Only approved raw materials are used. Our documentation system guarantees full lot traceability down to a single roll from a single batch. All quality related documents, production records and test reports are stored 5 or up to 10 years after production. Samples of every roll of each batch are stored for up to 5 years. Raw materials, intermediate products and final products are thoroughly tested in our laboratory for different chemical parameters and cytotoxicity. Test results are registered on a Certificate of Conformity supplied with every batch of material.
REGULATORY AFFAIRS

In order to enable our customers to register their end-users’ products, we have compiled a Master File (DMF) for most of the RENOLIT SOLMED products.

The Applicant’s Part of the DMF is available for the registration applicant. The Authority Part has been filed with the relevant National Health Authorities in many countries all over the world, including China, Europe, the USA, Russia and Japan. This strictly confidential part of the DMF can be used as a reference after our authorization has been provided. For registration assistance worldwide our Regulatory Affairs department is at our customers’ disposal.

DISCLAIMER

The data contained in this document are provided in good faith for the sake of general information. It is deemed to be accurate at the time of going into press. The purchaser or the user is required to verify with our technical services whether any specific application is appropriate.

Freedom of possession, use or marketing under intellectual property rights, or legal provisions or regulations, whether national or local, must be duly considered before use. Under no circumstances should any RENOLIT SOLMED film, tubing or compound be used in any cosmetic, reconstructive or any other temporary or permanent bodily implant application. The information provided in this document is subject to change without prior notice.
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