

# THE FUTURE OF **HEALTHCARE**

RENOLIT Healthcare作为雷诺丽特集团重要的市场单元,是高品质医 用级聚合物产品的市场领导者、创新解决方案的提供者以及客户和 合作商在全球范围内可信赖的合作伙伴,我们致力于对人类的健康 事业做出突出贡献,携手共创医疗健康的新篇章——与健康同行。

**RENOLIT** Healthcare is a Strategic Market Unit of the **RENOLIT Group**. As the market leader in medical-grade high-value polymer products, an innovative solution provider, and a global sparring partner for our customers and our partners, we are making vital contributions to human health. Together we take healthcare to the next level – Together Towards Health.



产原材料的闭环系统并引入节能产线。正如我们最 先进的挤出工艺技术就可以显著减少原料的使用。

We embrace our responsibility for today's and tomorrow's generations. By minimizing our carbon footprint, researching closed-loop system of manufacturing raw materials using CO<sub>2</sub> and sunlight and inventing resource-saving production cycles. Like our Extrusion Modeling Technology which significantly reduces raw material usage.

With **RENOLIT** Healthcare's four global production sites, we offer back-up production for our key products if desired by our customers. This way, challenges at one site do not hamper agreed delivery



# 生物工艺产品 BIOTECHNOLOGY

# 主要优势 KEY BENEFITS

## 全球生物制药行业在过去十几年间迅猛发展。

今天,一次性使用解决方案(SUS)已广泛地应用于生物制药领域中。与重复性使用解决方案(MUS)相比,SUS可帮助生物制药企业:

### THE GLOBAL BIOPHARMACEUTICAL INDUSTRY HAS BEEN GROWING FAST FOR DECADES.

Today, single-use systems (SUS) are increasingly used in biopharmaceutical field. Compared to multi-use systems (MUS) such as stainless steel processing containers, SUS can help biopharmaceutical companies to:

1	2	3	4	5
减少投资	缩短厂房设施的建设 周期并降低技术复 杂程度	减少乃至消除在线清 洗/在线灭菌以及对 应的质检	改进设施的利用时间	支持更灵活的生产 规模
Reduce capital cost	Shorten the facility construction time and lower the technical complexity	Minimize or eliminate the need of cleaning in place (CIP) / sterili- zation in place (SIP) and relative analytical quality controls	Improve the facility utilization time	Support a more flexible production scale

作为BPSA的成员以及生物技术领域知名的材料供应商之一,RENOLIT为一次性生物工艺行

一,RENOLIT为一次性生物工艺行业提供高质量的薄膜、软管及塑料颗粒,其应用包括培养基储存袋、生物反应器袋、搅拌系统、取样袋、冻融袋、罐装袋、冻存袋等,产品适用于辐照灭菌。

Being a member of BPSA (BioProcess Systems Alliance), **RENOLIT** Healthcare provides high-quality films, tubing & granules, for manufacturing single-use bioprocessing systems (media storage bags, bioreactors, mixing systems, sampling and product storage containers and so on). These components have to fulfill the severe and strict product properties that are required for critical biotechnology and pharmaceutical applications, and withstand radiation sterilization.

除具备完善的物理、化学及生物相容性检测报告及各类合规声明外,RENOLIT生物工艺产品还进行了大量严苛的可提取物研究,确保产品极低的可提取物及浸出物水平。

In addition to complete test reports on physical, chemical, biocompatibility and statements confirming to relevant laws and regulations, extensive strict extractable studies have also been conducted to ensure ultra-low extractable and leachable level of these products.

RENOLIT INFUFLEX生物工艺膜宽幅均大于1300mm, 匹配各种规格和体积的2D、3D袋设计, 并呈现出绝佳的高透明度, 利于应用环节的视觉观察与检测。

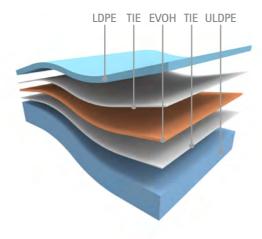
In a width more than 1.3 meters, these films are suitable for 2D and 3D bag design. In addition, **RENOLIT** INFUFLEX barrier films exhibit unprecedented high clarity favorable for visual inspection.



# 多层共挤高阻隔膜 MULTILAYER CO-EXTRUSION BARRIER FILM **RENOLIT INFUFLEX 9101**

RENOLIT INFUFLEX 9101已服务于全球生物市场超过15年,备 受全球SUS制造商、生物制药公司认可,并拥有众多生物工艺 应用方面的背书,是包括储液袋、配液袋、取样袋、一次性生 物反应器,以及转移袋、冻融袋、灌装袋等原液和非原液领域 应用在内的首选生物膜。

**RENOLIT** INFUFLEX 9101 has over 15 years experience serving the global bioprocessing market. The film is widely accepted by numerous global SUS system manufacturers and biopharmaceutical companies with abundant successful and proven experience. RENOLIT INFUFLEX 9101 is the best choice for many applications, such as media storage bags, bioreactors, mixing systems, sampling and product storage containers.



### 产品特点 PRODUCT FEATURES

- » 97%高透明度,便于在实际应用中对溶液进行目
- » 阻隔性能好,极低的氧气透过率,绝佳的顶空以 及溶液气体浓度控制;
- » 完善的物理、化学、生物相容性以及更严苛的E/L 测试,检测结果符合最严苛的行业标准;
- » 严谨的质量体系、充足的原料供应及稳定的生产 工艺,使得RENOLIT INFUFLEX 9101成为业内最安全 和可靠的选择。
- » High clarity of 97% to facilitate visual inspection of
- » Perfect barrier property with lower oxygen transmission rate, enabling better concentration control of the atmosphere in headspace and solutions;
- » Complete reports on physical, chemical and biocompatibility and strict BPOG E/L tests conforming to the strictest industry standards;
- » Rigorous quality system, reliable raw material supply, multi-continent production facilities and stable production process.

### 物理参数 PHYSICAL PROPERTY

		1	l结果 lue
检测项目 Item	检测标准 Procedure	GAMMA辐照前 Before Gamma Sterilization	GAMMA辐照后 After Gamma Sterilization
透明度 Clarity	ASTM D-1003	97%	97%
拉伸强度 Tensile Strength at Break	ASTM D-882	14Mpa	13Mpa
断裂拉伸率 Elongation at Break	ASTM D-882	280%	300%
水蒸气透过率 Water Vapor Transmission Rate	ASTM F-1249	0.35g/m2.day (23°C, 100% RH)	0.32g/m2.day (23°C, 100% RH)
氧气透过率 Oxygen Transmission Rate	ASTM D-3985	<0.05cm3/(m3.day.bar) (23C, 0% RH)	<0.05cm3/(m3.day.bar) (23C, 0%RH)

### 药典合规性及生物相容性 PHARMACOPOEIA COMPLIANCY AND BIOCOMPATIBILITY

	检测标准 Procedure	检测项目 Item	检测标准 Procedure
与血液相互作用试验 Hemolysis	ISO 10993-4	细菌内毒素测试 Bacterial Endotoxins – LAL Test	USP <85>
体外细胞毒性测试 Cytotoxicity	ISO 10993-5	体外生物反应测试 Biological Reactivity Testing, in Vitro	USP <87>
植入后局部反应试验 Implantation Test	ISO 10993-6	体内生物反应测试 Biological Reactivity Testing, in Vivo, Class VI	USP <88>
刺激与致敏试验 Irritation and Sensitization Tests	ISO 10993-10	化学项验证 Plastic Container	USP <661>
全身毒性试验 Acute Systemic Toxicity Test	ISO 10993-11	欧洲药典- 材质验证 European Pharmacopoeia Tests	Ch.3.1.5.

# 多层共挤高阻隔膜 MULTILAYER CO-EXTRUSION BARRIER FILM **RENOLIT SUSFLEX 9101**

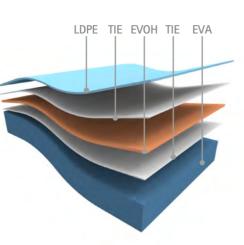
### 产品特点 PRODUCT FEATURES

- » 与RENOLIT INFUFLEX 9101相同原料,是实现安全、稳定、 » Same raw materials as RENOLIT INFUFLEX 9101, making 可确保供应的生物膜国产化方案。
- » 与RENOLIT INFUFLEX 9101相同的性能和应用,更低的成
- » 本地化生产保证产品稳定供应和更短的供应链。
- it a safe, stable and supply-sufficient option for domestic
- » Similar properties and same applications as RENOLIT INFU-FLEX 9101.
- » Domestic production at RENOLIT Healthcare Beijing ensures product availability and short supply chain.

# 多层共挤高阻隔膜 MULTILAYER CO-EXTRUSION BARRIER FILM RENOLIT BF1400C

## 产品特点 PRODUCT FEATURES

- » RENOLIT BF1400系列的新产品,深受全球众多生物制药公司的认可。
- » 更为柔软,与支撑容器更为贴合。
- » 完善的物理、化学、生物相容性以及更严苛的E/L测试,检测结果真实优异。
- » EVA材质液体接触层适用于广泛的一次性使用系统及波浪式生物反应器。
- » New product of RENOLIT BF1400 series, which is well recognized and accepted by many pharmaceutical companies.
- » Softer, making it more fit for the holder.
- » Complete reports on physical, chemical and biocompatibility and strict E/L tests showing real and excellent results
- » Flexible EVA contact layer suitable for a wide range of single use systems and rocking table bioreactors



### 物理参数 PHYSICAL PROPERTY

检测项目 Item	检测标准 Procedure	检测结果 Value
透光率 Transmittance	ASTM D-1003	88%
拉伸强度 Tensile Strength at Break	ASTM D-882	17Mpa
断裂拉伸率 Elongation at Break	ASTM D-882	800%
水蒸气透过率 Water Vapor Transmission Rate	ASTM F-1249	1.58g/m2.day (23°C, 100% RH)
氧气透过率 Oxygen Permeability	ASTM D-3985	3.40cm3/(m3.day.bar) (23C, 0%RH)

### 药典合规性及生物相容性 PHARMACOPOEIA COMPLIANCY AND BIOCOMPATIBILITY

检测项目 Item	检测标准 Procedure	检测项目 Item	检测标准 Procedure
与血液相互作用试验 Hemolysis	ISO 10993-4	细菌内毒素测试 Bacterial Endotoxins – LAL Test	USP <85>
体外细胞毒性测试 Cytotoxicity	ISO 10993-5	体外生物反应测试 Biological Reactivity Testing, in Vitro	USP <87>
植入后局部反应试验 Implantation Test	ISO 10993-6	体内生物反应测试 Biological Reactivity Testing, in Vivo, Class VI	USP <88>
刺激与致敏试验 Irritation and Sensitization Tests	ISO 10993-10	化学项验证 Plastic Container	USP <661>
全身毒性试验 Acute Systemic Toxicity Test	ISO 10993-11	欧洲药典- 材质验证 European Pharmacopoeia Tests	Ch.3.1.7.

# 多层共挤不包含阻隔层生物工艺用膜 MULTILAYER CO-EXTRUSION NON-BARRIER FILM

# **RENOLIT LINERFLEX EASYFILL 7101C**

### 产品特点 PRODUCT FEATURES

- » 多层PE膜结构,不含添加剂及抗氧化剂,产品安全、 稳定。
- » 成本优势,是衬袋及投料袋应用的优选生物膜材。
- » 膜材表面不粘黏,易于灌装

» Multilayer PE film without additives and antioxidants, safe and stable.

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- » Lower cost, optimized option for liner and feeding bag
- » Non-stick surface to allow easy filling of the system

# PE管路 PE TUBING RENOLIT TUBEFLEX 4101

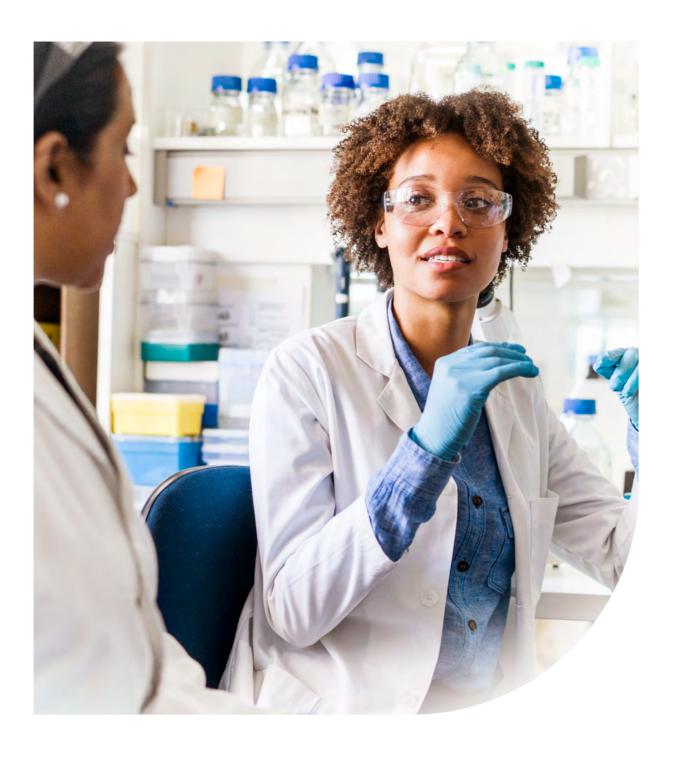
### 产品特点 PRODUCT FEATURES

- » 惰性PE材质,更易与RENOLIT INFUFLEX 9101、
  RENOLIT SUSFLEX 9101以及RENOLIT GRANUFLEX 4301
  进行焊接。
- » 常应用于代替小体积SUS软袋的袋扣,如取样袋;
- » 根据客户需求可提供丰富规格选择;
- » 具备完善的产品测试及完整的声明文件做应用支撑。
- » Inert PE material favorable for welding with RENOLIT INFUFLEX 9101, RENOLIT SUSFLEX 9101, and RENOLIT GRANUFLEX 4301
- » Often used as replacement of dip tube port for small SUS bag (such as sampling bag)
- » Inner and outer diameter adaptable to customer requirements.
- » Complete test reports and statements for application support.

# PE颗粒 PE GRANULE RENOLIT GRANUFLEX 4301

## 产品特点 PRODUCT FEATURES

- » 与RENOLIT INFUFLEX 9101液体接触层同源惰性PE材质, 用于注塑组件,更易与RENOLIT INFUFLEX 9101及 RENOLIT SUSFLEX 9101进行焊接。
- » 具备完善的产品测试及完整的声明文件做应用支撑。
- » Inert PE material favorable for welding with RENOLIT INFUFLEX 9101 and RENOLIT SUSFLEX 9101, used for bag component molding
- » Complete test reports and statements for application support.



# 冻存产品 CRYOPRESERVATION

# 主要优势 KEY BENEFITS

# 多年可靠的口碑积累 RELIABLE EXPERIENCE FOR YEARS

作为最早的冻存领域应用膜材供应商,RENOLIT Healthcare的产品凭借数十年的可靠应用经验以及稳定的供应能力,倍受全球众多冻存袋品牌认可。

As one of the earliest film suppliers in cryopreservation applications, **RENOLIT** Healthcare products gained broad acceptance from reputable cryopreservation companies based on decades of reliable experience.

# **2** 极佳的冻存应用表现 EXCELLENT PERFORMANCE IN FREEZING STORAGE

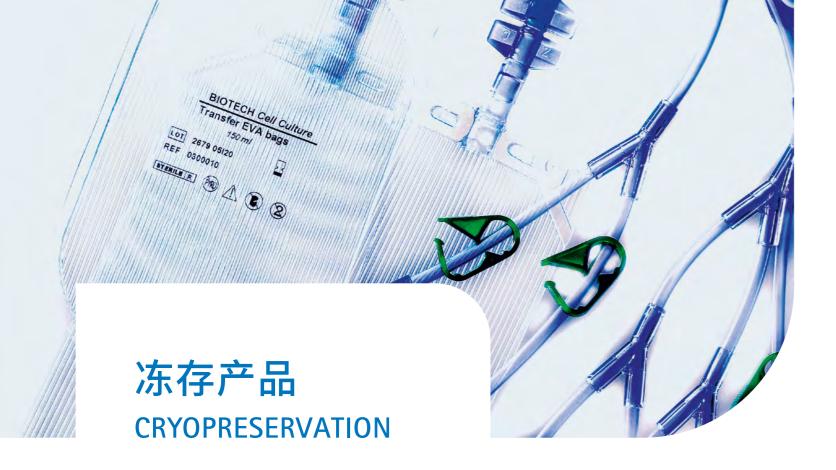
RENOLIT Healthcare冻存领域薄膜以EVA或聚烯烃弹性体混合物为材质,具备低至-196°C的极佳低温耐受能力,伴随着极高的氧气和二氧化碳透过率,非常适用于干细胞存储及基因治疗应用。

**RENOLIT** Healthcare's EVA or polyolefin cryopreservation films offer excellent low temperature tolerance capability down to  $-196^{\circ}$ C, feature high permeability of  $O_2$  and  $CO_2$ , these products are especially suitable for storage of stem cells and gene therapy applications.

# 主富的规格方案选择 ABUNDANT SPECIFICATIONS

依据应用类型的不同,RENOLIT Healthcare可提供多种花纹的筒膜、片膜及颗粒等规格和方案供客户选择。

Suitable for different applications, **RENOLIT** Healthcare provides both tubular and flat film as well as granule with various surface structures and specifications following customer requirements.



## 产品特点 PRODUCT FEATURES

- » RENOLIT Healthcare提供冻存袋应用的原材料的 » RENOLIT Healthcare provides integrated solutions 整体解决方案
- » 拥有完善的物理,化学,生物项测试,呈现出真实 且优异的结果表现,并且拥有完整的法规声明文 件做应用支撑。
- » RENOLIT的EVA材质与聚烯烃弹性体混合物的 膜/管路/粒料长期稳定供应全球冻存袋头部重 点客户。
- » 可实现的高质量表现,深受终端客户认可。

- for raw materials of cryopreservation bags
- » Complete reports on physical, chemical and biocompatibility showing real and excellent results, as well as required regulatory statements for application support
- » Long-term and stable supply for global top customers in cryopreservation field.
- » High quality, widely recognized and accepted by end users.

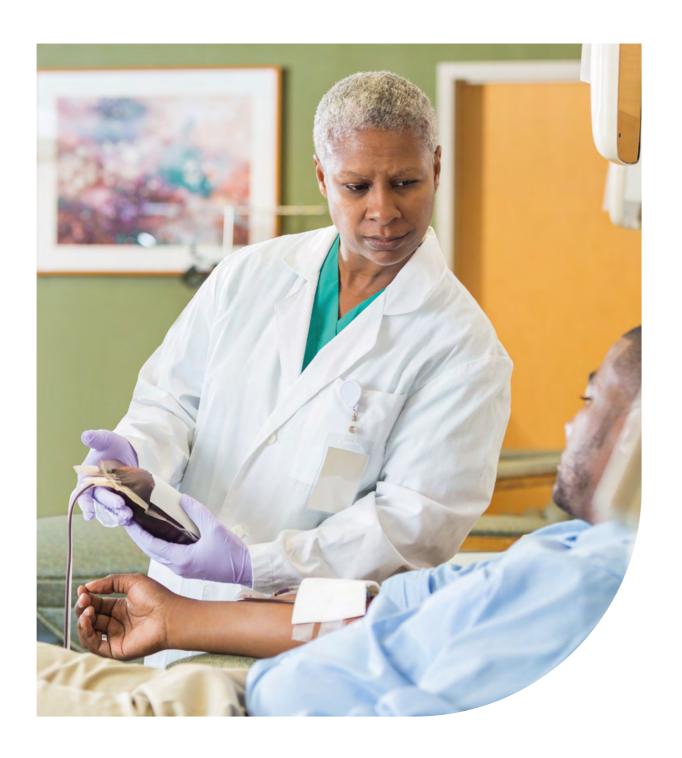
## 冻存产品 CRYOPRESERVATION 15

# 产品规格 PRODUCT SPECIFICATIONS

产品名称	规格	备注
Product	Specification	Remarks
RENOLIT MEDIPAK 0001 —	COMB – 120mm*0.35mm	细磨砂纹筒膜 tubular film with embossed surfaces
RENOLII MEDIPAK 0001 -	ISRB - 130mm*0.35mm	竖条纹筒膜 tubular film with ribs on the inner surface
RENOLIT TRANSFUFOL 0001	SETA - 550 mm *0.35mm	磨砂纹片膜 flat film with embossed surfaces
RENOLIT TRANSFUFOL 8300	SETA - 550 mm *0.35mm	磨砂纹片膜 flat film with embossed surfaces
RENOLIT MEDIGRANUUL 0002	350kg/托或25kg/袋 350KG/pallet or 25kg/bag	用于蝶形接口、折断塞及管路注塑 Used for butterfly port or Frangible and tubing extrusion
RENOLIT MEDIGRANUUL 0001	350kg/托或25kg/袋 350KG/pallet or 25kg/bag	用于蝶形接口、折断塞及管路注塑 Used for butterfly port or Frangible and tubing extrusion

# 药典合规性及生物相容性 PHARMACOPOEIA COMPLIANCY AND BIOCOMPATIBILITY

检测标准 Procedure
ISO 10993-4
ISO 10993-5
ISO 10993-6
ISO 10993-10
ISO 10993-11
USP <85>
USP <661.1>
Ch.3.1.7.



# 血液及血液成分包装 **BLOOD & BLOOD COMPONENTS**

# 主要优势 **KEY BENEFITS**

雷诺丽特是全球知名的血袋制造原材料生产商以及市场领导者。雷诺丽 特的血袋用薄膜被全球领先的血袋及血液处理系统的制造商所采用。这 里的血液处理系统包括单一血液成分采集与治疗。

> **RENOLIT** Healthcare is known as the worldwide market leader for the basic materials for the manufacturing of blood bag systems. The **RENOLIT** Healthcare blood bag films are supplied to the world's leading manufacturers of blood bags and blood processing systems including aphaeresis and therapeutic treatments.

雷诺丽特特殊研发的TRANSFUFOL薄膜加工技术结合了压延与挤出工艺的 优势,具有优异的批次间一致性。严格的洁净室条件、滤网清洗和在线切 割技术可以保证低颗粒物水平。

> The specially developed **RENOLIT** 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 slitting guarantee a low particulate level.

> > 雷诺丽特TRANS-FUFOL及INFUFOL 系列膜材用于生 产关键的血液接 触制品。

The **RENOLIT** TRANSFUFOL and INFUFOL films are used for the manufacturing of critical blood contact devices



雷诺丽特向客户提供多种符合 欧洲药典成分要求的可选配 方,如DEHP、TEHTM(或被称为 TOTM)、DINCH、DEHT、柠檬酸酯 增塑等。

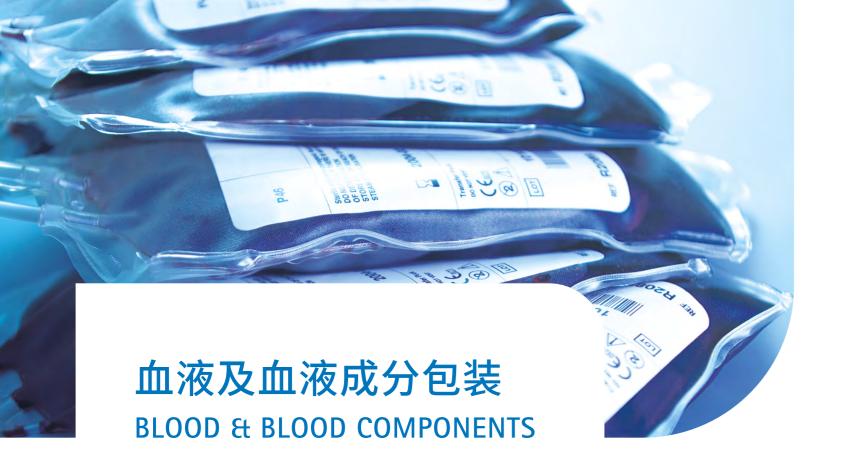
Various formulations are available, including DEHP, TEHTM, DINCH, DEHT and BTHC plasticized films following the composition requirements of the European Pharmacopoeia.

特殊的PVC或聚烯烃成分,可以为 血小板存储提供足够的氧气及二 氧化碳透过率,部分也可用于冷 冻或低温存储。

Special PVC and polyolefin based compounds offer high oxygen and carbon dioxide permeability for platelet storage, some formulations are also suitable for low temperature/ cold storage.

依薄膜类型不同,可提供厚度在 0.20-0.75mm, 宽度50-1350mm范 围内的产品。

Wide range with thickness of 0.20-0.75mm and width of 50-1350mm are available based on different film



## 产品特点 PRODUCT FEATURES

- » 经过长期验证, RENOLIT PVC Film适用于全自动产线且性能出众。
- » RENOLIT PVC Film长期稳定供应全球血袋以及医疗耗材领域的头部重点客户。
- » 高质量表现,深受终端客户认可。
- » 产能遍布全球,包括荷兰、美国及中国,生产经验丰富。
- » 非DEHP增塑剂的PVC膜,品规齐全,生产经验丰富且质量稳定。
- » RENOLIT应用范围广泛,血袋、血小板袋、HIPEC或镇痛泵药液袋等应用。
- » With proven experience for years, RENOLIT Healthcare PVC film shows excellent performance on automated blood bag production lines.
- » Long-term and stable supply for global top customers of blood bag and medical consumables sectors.
- » High quality, widely recognized and accepted by end users.
- » Production sites all over the world, including Netherlands, America and China with abundant experience
- » Complete specifications of Non-DEHP films with reliable production capacity and stable quality level.
- » Wide applications, such as blood bag systems, blood platelet storage bags, solution bags for HIPEC or analgesia pump.

# **RENOLIT TRANSFUFOL 3226**

#### 主要应用于血袋以及CGT相关应用。

Mainly used for blood bags and relevant applications of

# **RENOLIT TRANSFUFOL 3700**

非DEHP的BTHC增塑剂PVC膜,高氧气及二氧化碳透过率,是包括混合浓缩血小板和单采血小板在内的血小板储存袋用PVC膜的首选。

Non-DEHP PVC film with BTHC plasticizer, high oxygen and carbon dioxide permeability, best PVC choice for storage bag of blood platelets, including pooled platelets and apheresis platelets.

## **RENOLIT TRANSFUFOL 3224**

非DEHP的TEHTM增塑剂PVC膜,适用于至多5天血小板储存袋。

Non-DEHP PVC film with TEHTM plasticizer, suitable for up to 5-day storage bag of blood platelets

## **RENOLIT TRANSFUFOL 3126**

非DEHP增塑剂PVC膜,是目前应对"欧洲DEHP Sunset"的首选。

Non-DEHP PVC film with DEHT plasticizer, best choice following "Europe DEHP Sunset" at present.

# RENOLIT INFUFOL 3800/3801

本地化生产,主要应用于血袋以及CGT相关应用。

Mainly used for blood bag systems and relevant applications of CGT, manufactured locally.

# **RENOLIT INFUFOL 3824**

本地化生产,非DEHP增塑剂PVC膜,主要应用于医疗设备临时药液承装袋以及5天血小板储存袋。

Non-DEHP PVC film, used for temporary solution bag for medical equipment and 5-day storage bag of blood platelet, manufactured locally.

# **RENOLIT INFUFOL 3842**

本地化生产,非DEHP的DINCH增塑剂PVC膜,主要应用于血袋及医疗设备临时药液承装袋。

Non-DEHP PVC film with DINCH plasticizer, used for blood bag systems and temporary solution bag for medical equipment, manufactured locally.

# RENOLIT Healthcare——布局全球,致力于向全世界客户供应原材料

RENOLIT Healthcare – GLOBAL PRESENCE AND GLOBAL RAW MATERIAL SOURCING FOR GLOBAL CUSTOMERS



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