

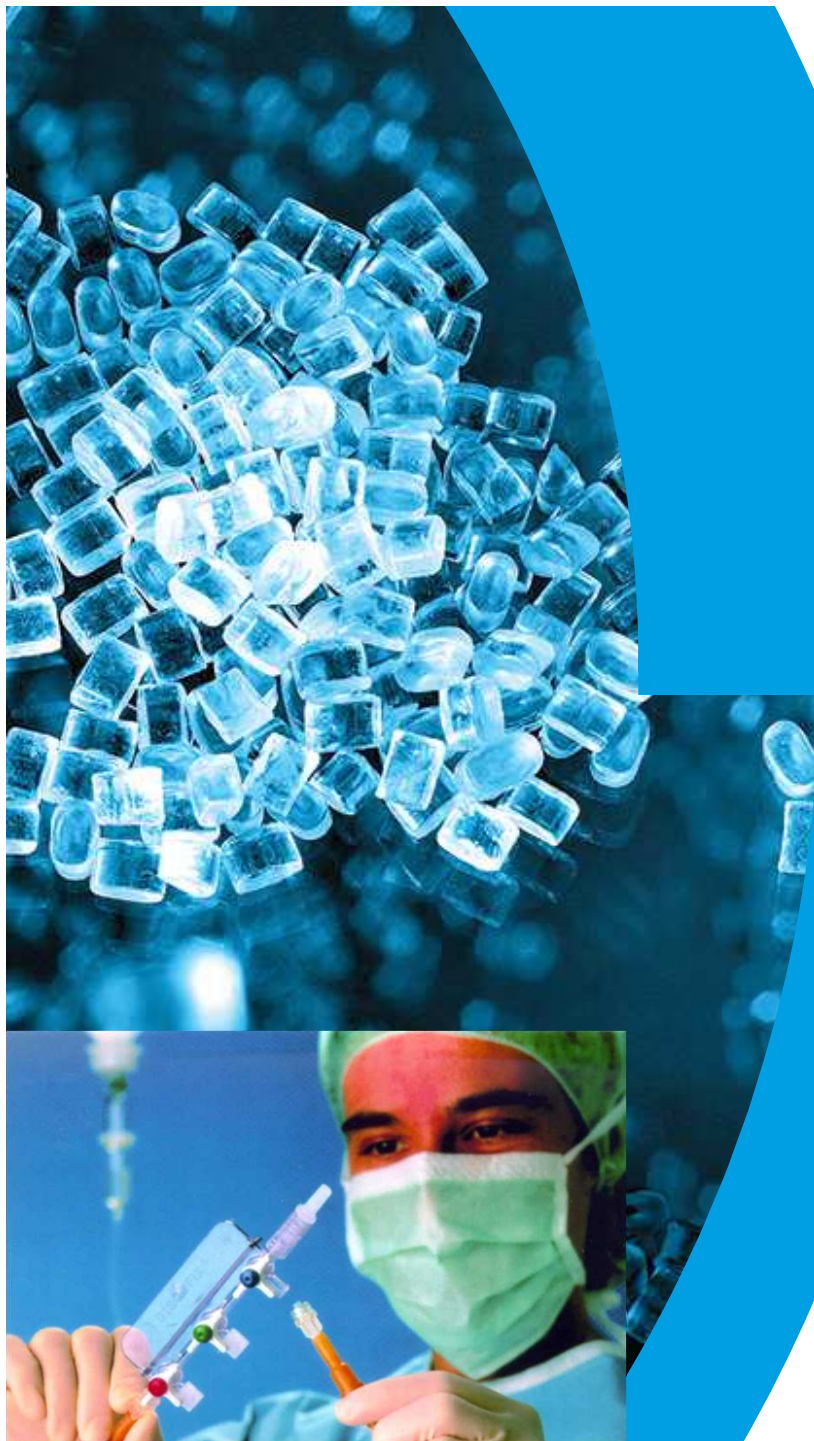


Covestro Polycarbonate Technical Solution for Medical Device

科思创聚碳酸酯在医疗器
械的应用技术
For KDF

covestro.com

INTERNAL





Agenda 议题内容

□ Covestro Medical Polycarbonate Properties Overview

科思创医疗级聚碳酸酯的特性

□ Covestro Innovative Polycarbonates for Medical Devices Solution

科思创的创新材料对医疗设备解决方案

INTERNAL

COVESTRO 科思创



- ❖ **Formally as Bayer Materials Science.**

科思创前身为拜耳材料科技，隶属于拜耳集团公司。

- ❖ **Annual revenue reach to €14 Billion at 2017.**

科思创是全球最大的聚合物生产公司之一，其**2017**年度销售额达**140**亿欧元。

- ❖ **Active in Automotive, Electric, Medical, Construction**

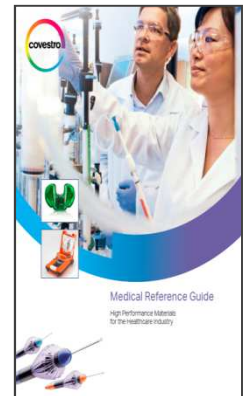
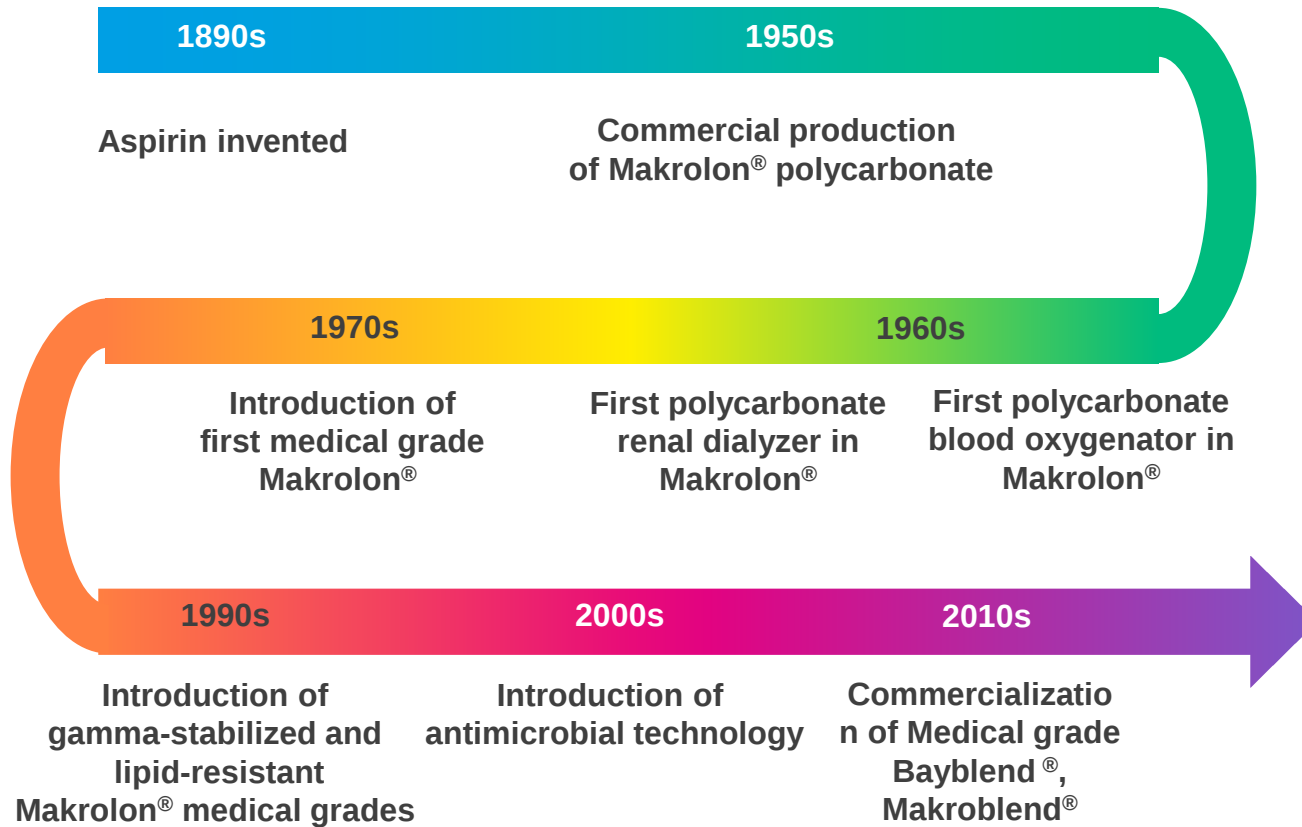
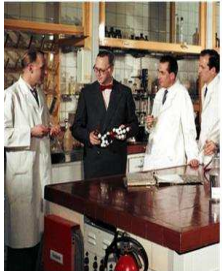
所服务的行业主要包括：汽车、电子和电气、医疗、建筑、体育和休闲。

- ❖ **There are 30 manufacture site and 15700 employees.**

截至**2015**年底，科思创在全球拥有**30**个生产基地、约**15,700**位员工。

INTERNAL

Inventor of Polycarbonate with a Long History in Medical



Our Medical Portfolio is Carefully Managed to Deliver Reliability and Quality Worldwide

INTERNAL

PC in main applications

聚碳酸酯：主要应用行业



汽车制造 Automotive

基建 Construction

电子/电气 E/E

医疗应用 Medical

休闲日用产品 Consumer

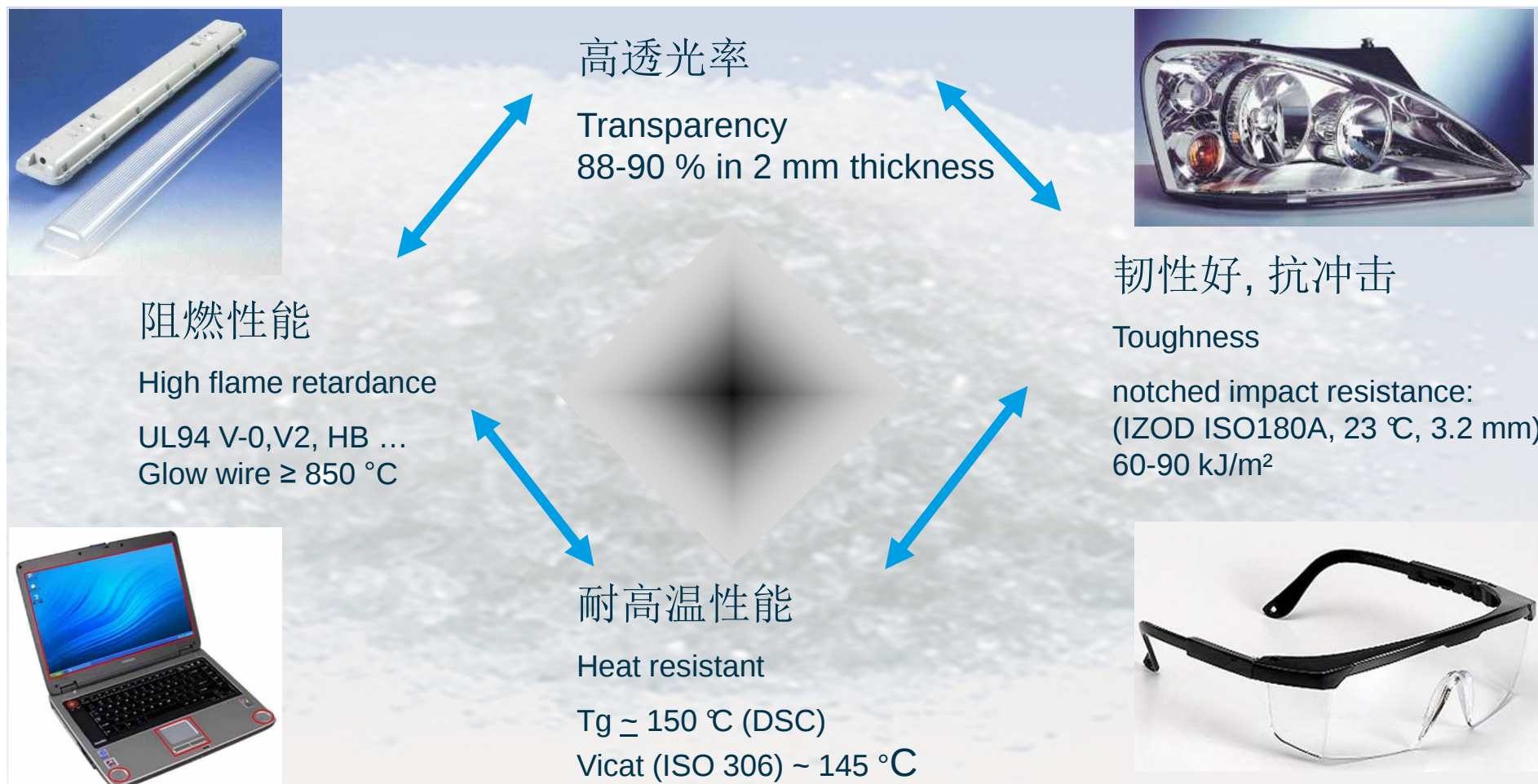
光学应用 Optical

包装 Package



INTERNAL

聚碳酸酯材料特性



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Brand of Polycarbonate

科思创聚碳酸酯在医疗行业的材料



Makrolon®

Polycarbonate

模克隆®聚碳酸酯



Bayblend®

PC/ABS

拜本兰® PC/ABS合金



Makroblend®

PC/Polyester blend

模克本兰® PC/聚酯合金



Apec®

High Heat Co-PC

亚霸®高温PC共聚物

INTERNAL

Biocompatibility 生物相容性

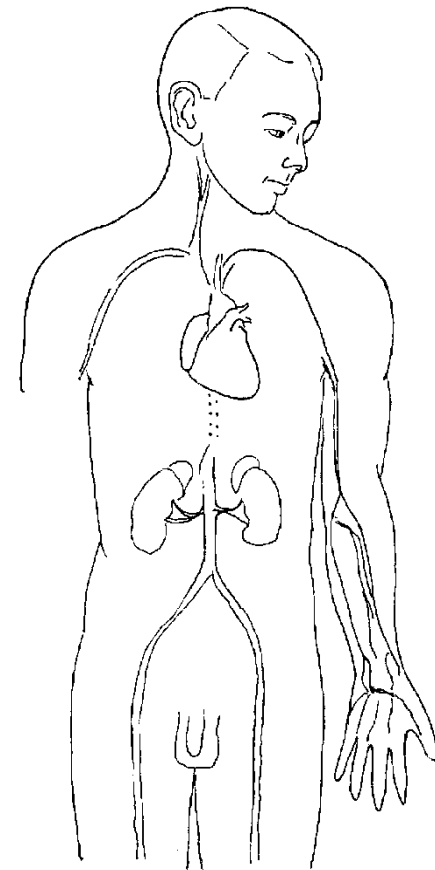


生物相容性材料证书是医疗设备生产商重要考虑因素

Key Documents in Product Registration

在材料上做的毒物学试验是按照ISO-10993-1 和美国药典 VI 级别进行

1. **Acute System Tox.** 敏锐系统毒性试验
2. **Intracutaneous Tox.** 皮内毒性试验
3. **Muscle Implantation** 肌肉培植试验
4. **Cytotoxicity** 细胞毒性试验
5. **Hemolysis Direct and Extraction** 溶血和萃取试验
6. **Pyrogen Study** 热原质研究
7. **Sensitization** 至敏性
8. **Mutagenicity** 诱变性
9. **Heavy Metal Analysis** 重金属分析
10. **Physicochemical Tests** 物理化学试验



INTERNAL

YY/T 0806 医用聚碳酸酯专用料



Medical PC is the trend in China.

医用级聚碳酸酯已在中国医疗器械中普及使用.

PC standard effected since 2012

医用级聚碳酸酯专用料行业标准已于2012年六月生效

ICS 11.040.20
C 31

YY

中华人民共和国医药行业标准

YY/T 0806—2010

医用输液、输血、注射及其他医疗器械
用聚碳酸酯专用料

Polycarbonate material for manufacture of infusion,transfusion and injection
equipments for medical use and other medical devices

2010-12-27 发布

2012-06-01 实施



国家食品药品监督管理局 发布

...TERNAL

GB9685-2016 食品容器、包装材料用添加剂使用卫生标准



许可序号	化学品名称	CAS no.	最大使用量%	特定迁移量/最大残留量 (SML/QM)	特定组迁移量 (SML(T))	SML(T)	备注
FCA0381	颜料号：溶剂红 111 (C. I. solvent red 111)	82-38-2	聚苯乙烯、丙烯腈-苯乙烯聚合物、丙烯腈-丁二烯-苯乙烯聚合物、聚酰胺(尼龙)、据对苯二甲酸乙二醇酯、聚碳酸酯 ABS、PS, AS, ABS, PA, PET, PC: 0.2				符合重金属要求 Heavy metal requirements



Additives in food
INTERNAL
Contact

Compliance support from COV

科思创对医疗设备生产商的法规支持



- 生物相容性

Biocompatibility: ISO 10993-1 and USP Class VI for contact of 30 days or less

- FDA 医药主名册

Maintenance of FDA Drug Master File (DMF) and Letters of Authorization

- GMP 生产线

Manufactured at certified GMP sites

- 产品配方变动通知

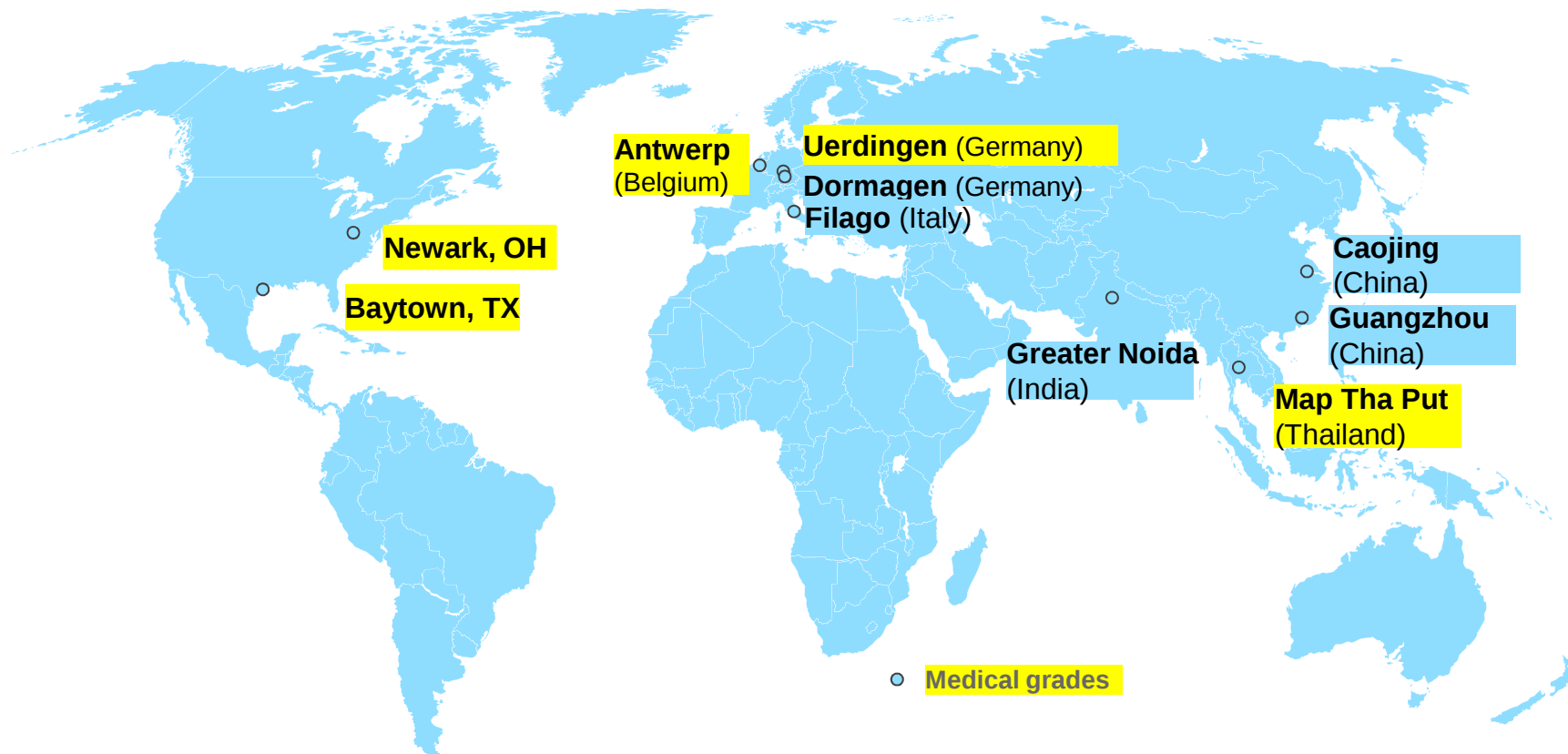
Supplier notification of change



INTERNAL

Global Supply

全球供应- 更快的运输和更低成本



科思创全球有多个生产基地可供应医用级产品

产能150万吨，全球第一

INTERNAL

Guidelines

使用科思创医用高分子材料的指引



Covestro does not permit the use of its resins in any cosmetic or reconstruction or reproductive implant application.

科思创不允许对其材料进行外观或性能上的改变而重新造粒，或将回收料用于医疗用途。

Covestro resins are unsuitable for bodily implant applications greater than 30 days, based on the FDA-modified ISO 10993-1.

基于由**FDA**而来的**ISO 10993-1**标准，科思创的医用高分子材料在用于和人体植入接触时，使用时间不能超过**30**天。

The number of sterilization cycles a part made from a Covestro resin can withstand will vary depending upon the resin type/grade, part design, service temperature, chemical environment, sterilization technique, and/or processing parameters.

用科思创材料生产的部件可以承受的消毒周期数，取决于所用原料的类型/品级，产品设计，使用温度，化学环境，消毒工艺和/或加工参数等等。

INTERNAL



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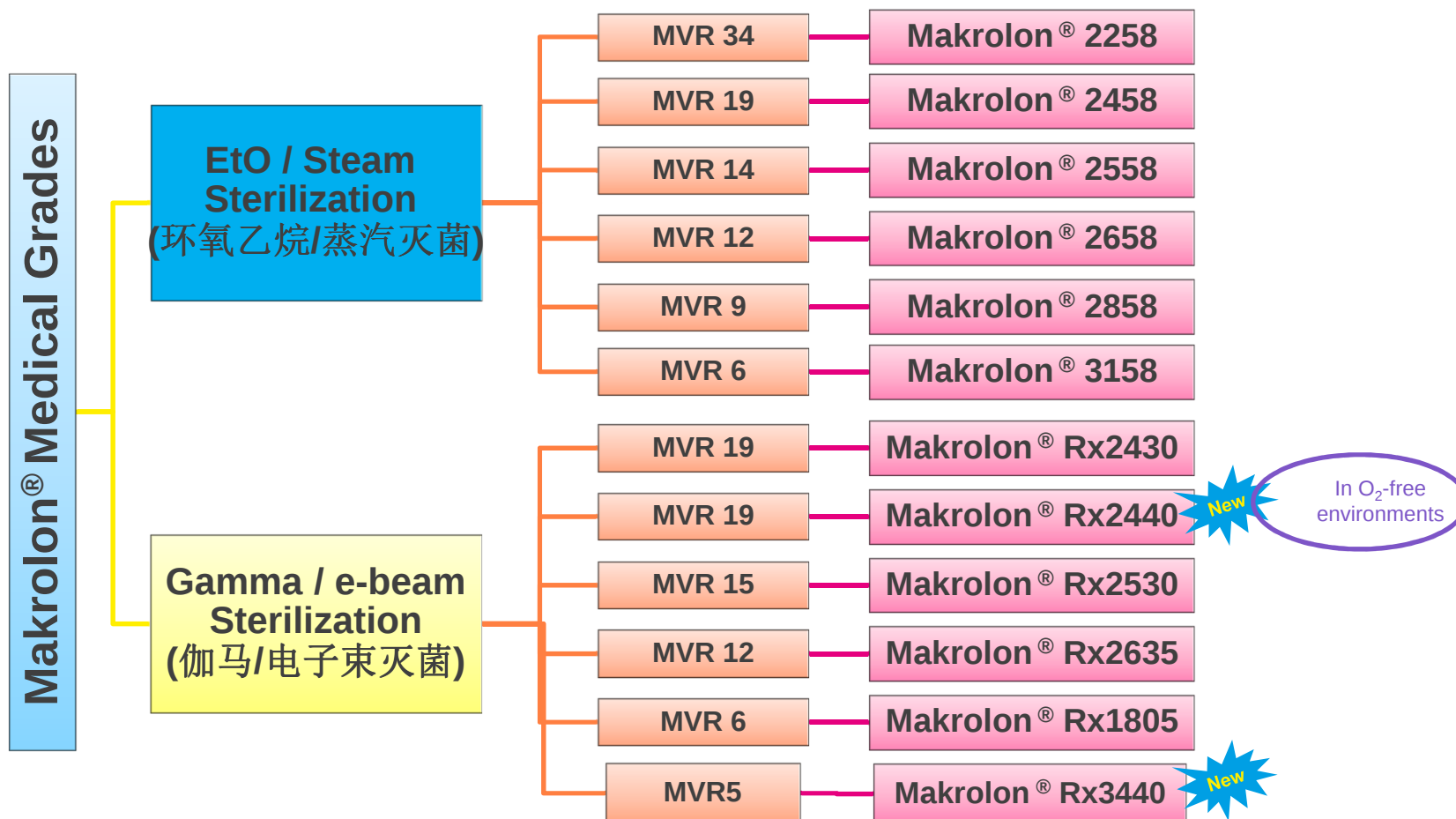
❑ Technical Support to Medical Device Customers

科思创对医疗设备客户的技术支持服务

INTERNAL



Medical Grade 模克隆医疗产品等级



Sterilization



聚碳酸酯材料可使用的灭菌方法

	环氧乙烷 Ethylene Oxide Sterilization	伽马射线 Gamma Radiation	电子束 Electron Beam Radiation	121℃ 蒸汽 Steam Autoclave	143℃ 蒸汽 High-Heat Steam
Makrolon PC	Yes	Yes	Yes	Yes	No
Apec High-Heat PC	Yes	Yes	Yes	Yes	Yes
Bayblend PC/ABS	Yes	Yes	Yes	No	No
Makroblend PC/Polyester	Yes	Yes	Yes	No	No

Source: In-house testing

INTERNAL

Dialyzer 肾病透析应用



Dialysis 透析系统



Dialyzer 透析管外壳



胆固醇吸收系统

各种不同规格模克隆

INTERNAL

Dialyzer 肾病透析应用



Dialysis 透析系统

M. 2858
RX 2430



Dialyzer 透析管外壳

M.2458

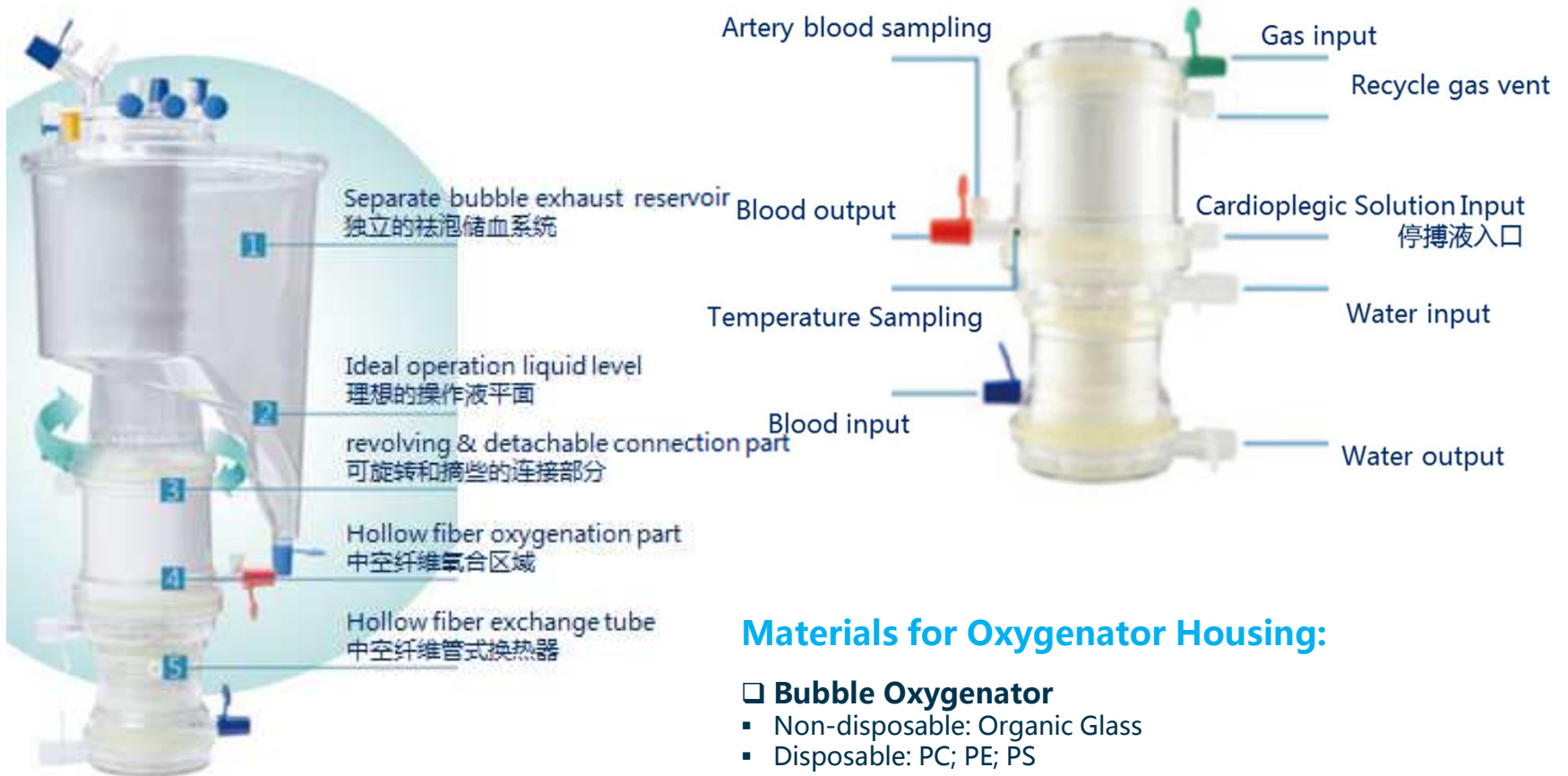


胆固醇吸收系统

各种不同规格模克隆

INTERNAL

Oxygenator 储血器和氧合器应用



Materials for Oxygenator Housing:

❑ Bubble Oxygenator

- Non-disposable: Organic Glass
- Disposable: PC; PE; PS

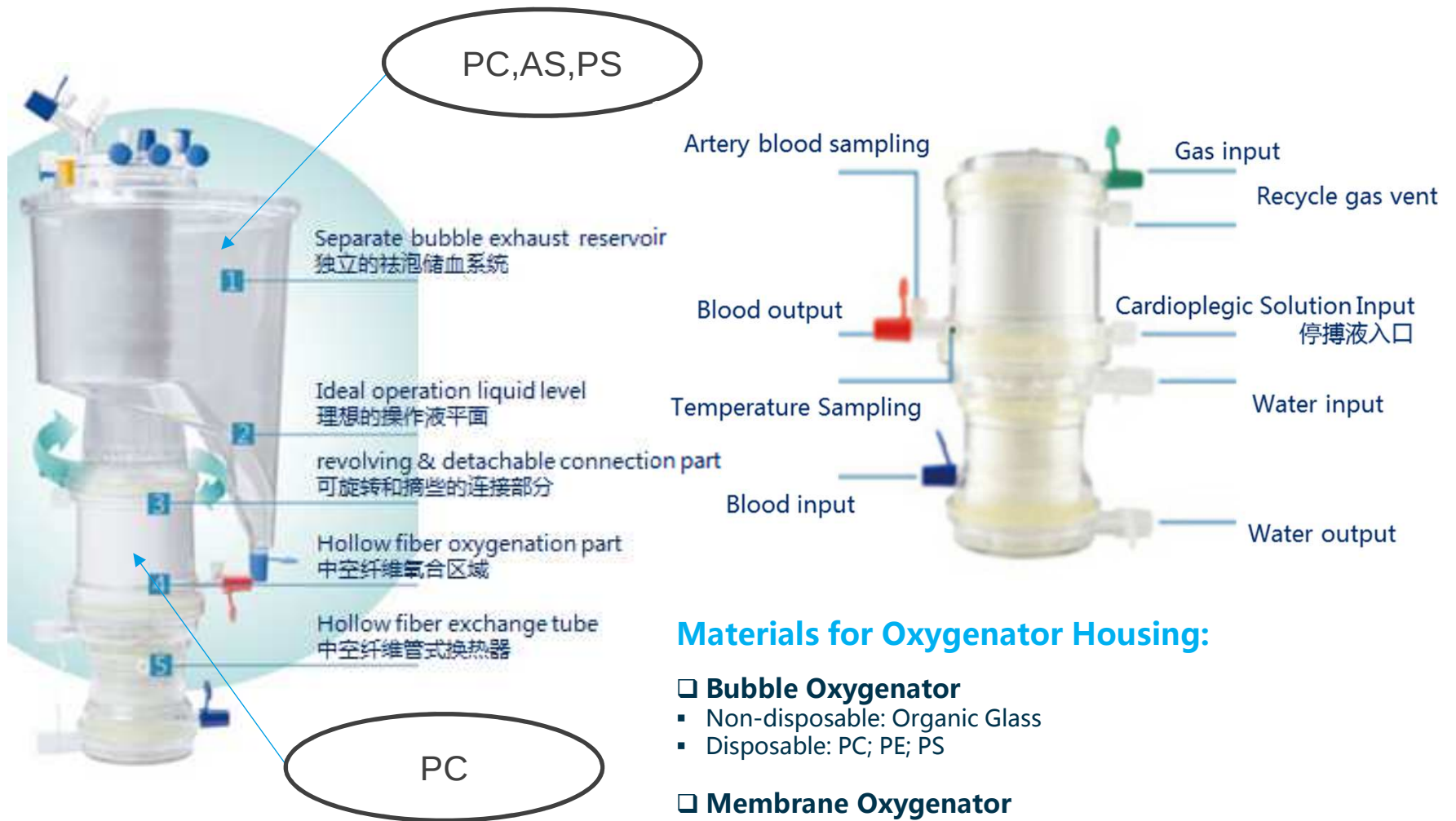
❑ Membrane Oxygenator

- **PC & PS**



oxygenator
INTERNAL

Oxygenator 储血器和氧合器应用



Materials for Oxygenator Housing:

❑ Bubble Oxygenator

- Non-disposable: Organic Glass
- Disposable: PC; PE; PS

❑ Membrane Oxygenator

- **PC: M.2858**

INTERNAL

IV access systems

静脉输液接入系统



Needleless access connector
(滴液联接器)



Enteral feeding pump
(营养输注泵接口)



Luers and stopcocks
(鲁尔接口和开关)



Manifolds
(输液阀门组)



Intravenous
sions 3 ways Stopc



IV Safepole BB
FR3010

IV access systems

静脉输液接入系统



RX 1805



Needleless access connector
(滴液联接器)



Enteral feeding pump
(营养输注泵接口)



Luers and stopcocks
(鲁尔接口和开关)



Manifolds
(输液阀门组)



Rx1805?????



rx 1805 datasheet



Intravenous
sions 3 ways Stopc



IV Safepole BB
FR3010

Chemical Resistance

耐化学医用材料

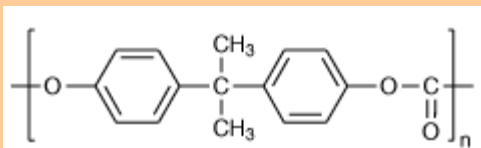


Polycarbonate PC + Polyester 聚酯

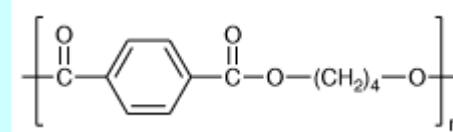
amorph 无定型

semi cristalline 半结晶

PC



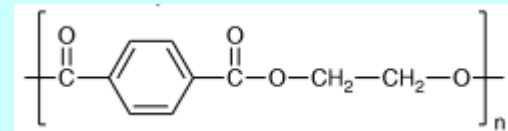
PBT



(Polybutylterephthalate)

or

PET



(Polyethylterephthalate)

makroblend®



chemical

resistance

Makroblend® PC + Polyester Blends



Classification	Grade	Description	Application Example
Standard	Makroblend® EC150	Flame-retardant (non-halogenated), Chemically resistant	Personal care equipment
	Makroblend® EL700	Flame-retardant, Chemically resistant	Monitors and Diagnostic Equipment
	Makroblend® EL703	Flame-retardant, UV Stable, Chemically resistant	Monitors and Diagnostic Equipment
Skin Contact Biocompatible	Makroblend® M4000 FR 	Flame-retardant, Superior chemical resistance	Monitors and Diagnostic Equipment for Surgery
	Makroblend® M525 	Chemically resistant for wearables	Drug Delivery Devices



Ultra-tough and resistant to chemicals for demanding applications

Durability Through Improved Chemical Resistance



Equipment housing materials need to resist disinfectants as hospitals use more aggressive disinfectants

- Improved chemical resistance, FR-resin for housings
- High modulus and high ductility for demanding applications

Property	Bayblend FR3010	Makroblend EL700 / EL703	Makroblend M4000 FR	Makrolon FR6006
Melt Index	20 ¹	25 ²	19 ²	10 ²
Tensile Modulus (MPa)	2620	2300	2290	2000
Chemical Resistance	★	★★	★★★	★★★★
FR rating (2.0) ³	V-0	V-0	V-0	V-0

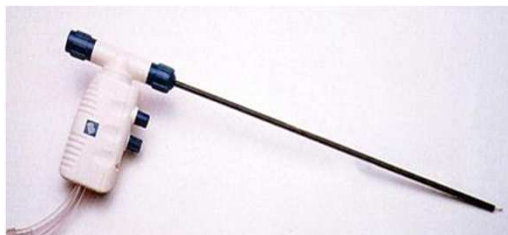


1. Measured at 240°/5; 2. Measured at 260°/5; 3. For details, consult the yellow card at www.ul.com

Surgical 手术器械



Ophthalmic micro forceps
and scissors
(眼科微钳和微剪)



Laparoscope
(内窥镜)



Inflator pump
(增压泵)



Knee balancer



Difibrillator
(除颤器)



Knee Balancer
(平衡仪)



Trocars
(穿刺器)

INTERNAL

Surgical 手术器械

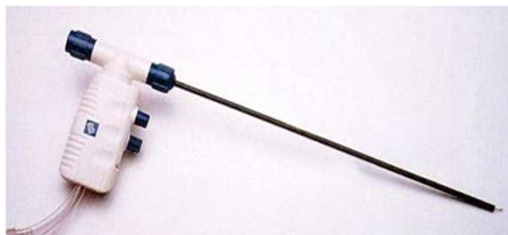


M.2458



Ophthalmic micro forceps
and scissors
(眼科微钳和微剪)

PC+GF



Laparoscope
(内窥镜)

FR 3010



Inflator pump
(增压泵)



FR 3010 for AED



Defibrillator
(除颤器)

FR 3010



Knee balance



Knee Balancer
(平衡仪)

RX.2430



Trocars
(穿刺器)

M.2858

INTERNAL

Respiratory 呼吸治疗



Respirator (呼吸机)+
Humidifier(湿化盒)



Mask (呼吸面罩)



Simple Respirator
(氧气吸入器)



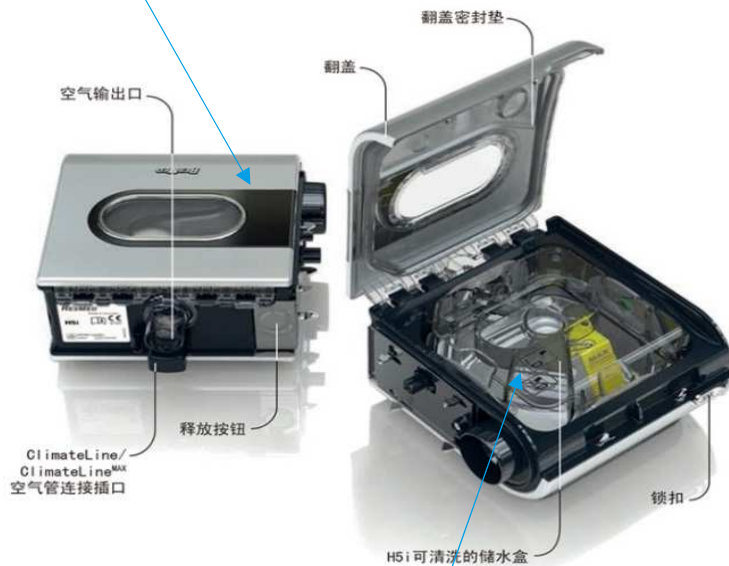
Simple Respirator
(简易呼吸器)

INTERNAL

Respiratory 呼吸治疗



PC/ABS for housing



Respirator (呼吸机)+
Humidifier(湿化盒)

M.2458 for Humidifer



Mask (呼吸面罩)

Apec.1745 over molding
silicon rubber



Simple Respirator
(氧气吸入器)

M.2458 pressure
bottle

M.2858 for connector



Simple Respirator
(简易呼吸器)

INTERNAL

Housing 轻量化医用电气设备材料



Bayblend PC/ABS 合金:

- ✓ 高尺寸稳定性容易加工
- ✓ High Dimension and easy processing
- ✓ 高流动性适合薄壁成型
- ✓ High Flow for thin wall
- ✓ 防水解和好的耐化学性
- ✓ Chemical resistance
- ✓ 符合 ISO10993 生物相容性测试
- ✓ Biocompatibility
- ✓ 防火级产品 FR
- ✓ 符合RoHS, WEEE要求



Potable oxygenator
便携型制氧机



Injection Pump
注射泵



MR or CT



Insulin Pump 胰岛素注射泵
INTERNAL

Housing 轻量化医用电气设备材料



Bayblend PC/ABS 合金:

- ✓ 高尺寸稳定性容易加工
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- ✓ Chemical resistance
- ✓ 符合 ISO10993 生物相容性测试
- ✓ Biocompatibility
- ✓ 防火级产品 FR
- ✓ 符合RoHS, WEEE要求

PC/ABS Sheet absorbing for large housing

FR 3010



Potable oxygenator
便携型制氧机

EL 4000



Injection Pump
注射泵



MR or CT

FR 303FR



Insulin Pump 胰岛素注射

M.301FR



Bayblend® PC+ABS Blends

Classification	Grade	Description	Application Examples
Standard	Bayblend® FR3000	Flame-retardant, Easy flow	Monitors and Diagnostic Equipment
	Bayblend® FR3010	Flame-retardant, high heat, improved impact resistance	
Skin Contact Biocompatible	Bayblend® M301FR	Flame-retardant, injection molding	At-home medical equipment
	Bayblend® M303FR	Flame-retardant, extrusion	
Biocompatible	Bayblend® M850XF	Good property balance, excellent part precision, high flow	Drug Delivery Devices
	Bayblend® M750	Superior toughness	



Bayblend: Innovative PC + ABS for Healthcare



limited Biocom PC/ABS

生物相容性拜本兰 M850XF



■ Characteristic 特性

- Comply with 合规 ISO 10993, USP Class VI
- High Flow 高流动性

■ Benefit 产品效益

- High Productivity 高生产率
- Stable dimension 产品尺寸稳定
- High Reliable 耐用性好

■ Applications 应用介绍

- Thin wall formulation 需要生物相容性要求的高流动性适合薄壁成型应用- 送药系统，手术设备.
- 胰岛素注射笔 Pre-loaded insulin pen housing



INTERNAL

Biocom FR PC/ABS-M301FR

防火级生物相容性拜本兰 M301FR



- Fire retardant and limited Biocom.
防火并且符合有限生物相容性要求
- Cytotoxicity, Skin sensitization, reactivity
细胞毒性, 致敏作用, 和刺激性测试
- High Dimension and easy processing
高尺寸稳定性容易加工
- High flow suit for thin wall
高流动性适合薄壁成型
- Eto and radiation
适用EtO, 辐照消毒

Makroblend M525 –for wearable

适用于穿戴型医疗设备



Anti Lotion and Cleaner, Meet ISO 10993-5 & 10

抗护肤液和清洁剂，有限度生物相容性 ISO10993-5, -10

性能	Bayblend® M850 XF	Makroblend® M525
MVR 熔融指数	25 cm ³ /10min	21 cm ³ /10min
Tensile Module 拉伸模量	2500	2000
Chemical 抗化学性	+	+++
Biocompatibility 生物相容性	ISO 10993-1	Skin friendly 適合皮肤接触

INTERNAL

Heat Resistance

高耐热医用级聚碳酸酯共聚物 – Apec 1745



- Biocompatibility

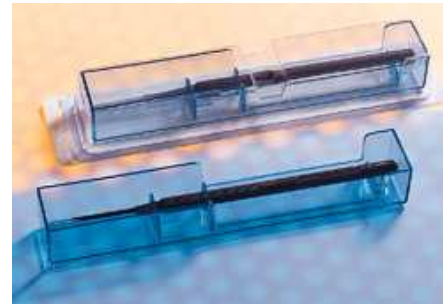
生物相容性 ISO10993

- Excellent Ductility

优异的韧性

- Transparency

优异的透明度



- E-beam/Gamma/Eto/143°C Steam

可经受电子束 / 伽玛 / 环氧乙烷和超高温蒸汽

消毒 143°C



Silicone Overmolding

Apec 1745 优化硅胶二次注塑



- High Temperature resistance in Overmolding

在二次注塑可用较高的模具温度

- Fast thermosetting time of Silicone under high temperature

硅胶在高模温下有较快的固化时间

- Enhance production efficiency

使用 Apec 能缩短硅胶注塑生产周期,
提高产能.



INTERNAL



Forward-looking statements

This presentation may contain forward-looking statements based on current assumptions and forecasts made by Covestro AG. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Covestro's public reports which are available on the Covestro website at www.covestro.com. Covestro assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments

INTERNAL



Thank You !!

主要的监管当局意见:

双酚A可安全地用于食品接触的应用中



欧盟食品安全管理局 (EFSA), 01-2015:
“接触双酚A无任何消费者健康风险¹⁾”



2012 开始重新评估

2013 暴露草案/
咨询公众意见

2014 人体健康草案/
咨询公众意见

2015 最终意见

CEF*小组: 20名来自大学/有关部门的专家, 从事:

- 风险评估
- 毒理学
- 新陈代谢
- 暴露
- 流行病学
- + 其它工作组进行
 - 双酚A毒理学 (28 名成员)
 - 双酚A暴露 (14 名成员)

1) <http://www.efsa.europa.eu/en/press/news/150121.htm?wtrl=01>



US FDA: “双酚A是否安全? 是的”²⁾
(2014年11月)

2) <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm355155.htm>

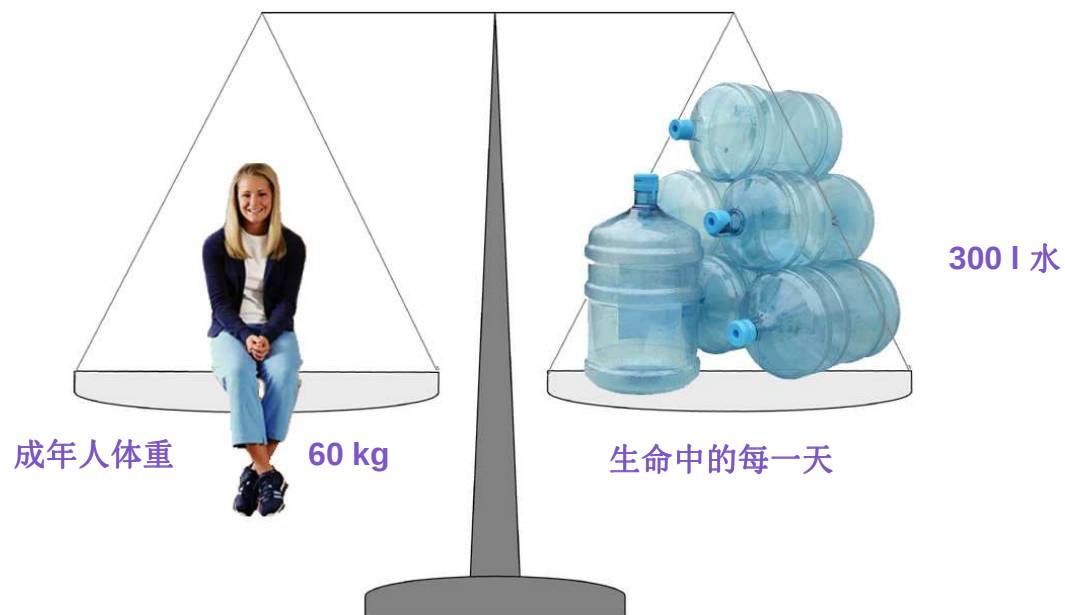
*CEF: EFSA 小组针对食品接触材料、酵母、
调味品和加工助剂

INTERNAL

消费者接触双酚A



欧盟监管机构安全限值vs. 典型暴露值 → 双酚A摄入量高于安全限值* 显然不可能



体重为60kg 的人需要饮用300升聚碳酸酯瓶装水才能达到安全限值*

*依据2015年1月21日刊登的EFSA最终意见:
<http://www.efsa.europa.eu/en/efsajournal/pub/3978.htm>

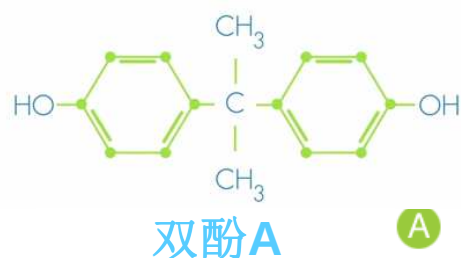
Makrolon Polycarbonate are a proven choice for the medical industry



- **Over 40 years of Makrolon in medical market**
- **Many application areas**
- **Proven record**

INTERNAL

双酚A——聚碳酸酯的重要组成成分



- 60多年来一直用作高科技塑料聚碳酸酯（PC）的组成成分
- 紧紧地结合在PC中——产品中仅含有痕量级未反应（自由）的双酚A
- 没有物质象双酚A那样经过全面研究，且物料特性上能取代双酚A-PC



科思创的双酚A立场

科思创坚信，目前没有任何科学依据能合理证明双酚A在消费者预期用途中存在任何健康或安全问题



科思创严格把关产品

- 由毒理学家组成的团队不断对新研究进行评审，特别关注对敏感人群的影响
- 如有任何双酚A或聚碳酸酯健康风险科学证据出现，我们将采取适当措施