



MEDICAL
医疗应用



SAFETY THAT'S CERTAIN
TO IMPRESS

安全至上 卓越品质

OUR COMPANY

BENEFITS IN ALL SHAPES AND SIZES

我们的公司

致力为各行各业提供优质热塑性弹性体 (TPE) 产品

Thermoplastic Elastomers (TPEs) are the materials used to make progress. Compounds from KRAIBURG TPE will open up all sorts of new opportunities in product development and processing making production efficient for you as well.

The solutions provided by KRAIBURG TPE will enable you to meet the highest requirements. Our company not only offers high quality specially custom-engineered products, but also provides a unique level of comprehensive customer service.

The company's motto, "CUSTOM-ENGINEERED TPE AND MORE", is meant to be taken literally. Our goal is to identify with you the challenges you face and support you at all times anywhere in the world.

热塑性弹性体 (TPE) 是实现产品改进的重要材料。凯柏胶宝® 的化合物将为产品开发和加工开辟出全新的可能，让您的生产效率更加出色。

凯柏胶宝® 的TPE解决方案将竭力满足您的全部要求。我们公司不仅提供高品质的特殊定制产品，还用心提供全面而独家的客户服务。

公司一言一行，都在贯行“不只是定制 TPE”的座右铭。我们的目标是：与您携手，明确当前挑战，在世界各地随时随地为您提供支持。



Regional Headquarters
区域总部

Buford (GA) USA
布福德(乔治亚州)/美国



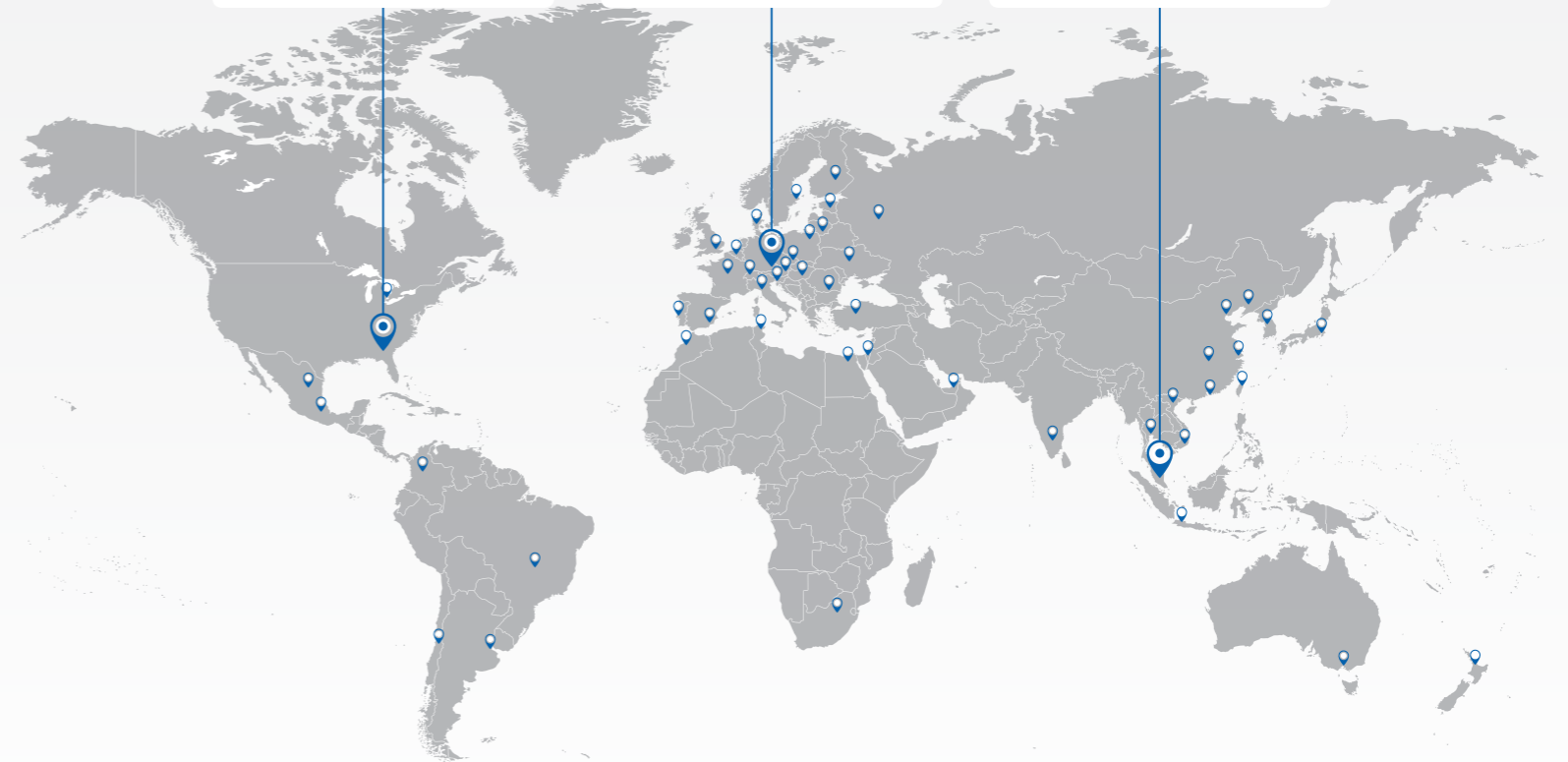
Headquarters
总部

Waldkraiburg GERMANY
瓦尔德克赖堡/德国



Regional Headquarters
区域总部

Kuala Lumpur MALAYSIA
吉隆坡/马来西亚





THE MARKET

MAKE THE SAFE CHOICE

市场

您的安全之选

Meeting the highest standards for quality and responsibility is an absolute necessity in the market for medical and pharmaceuticals technology.

That's why KRAIBURG TPE has implemented a quality management system that ensures compliance with the strictest requirements in the development, production, and handling of medical-grade plastics (MGP).

The THERMOLAST® M series supplies compounds that have been specially developed for applications in the medical, pharmaceutical and diagnosis sectors. They can even be used in direct contact with body fluids and blood. For the processor and the end customer, the change control management system that we have implemented and are actively putting into practice ensures that vital requirements are met.

在医疗和制药市场中，符合质量标准至关重要。

因此，凯柏胶宝®实施了严格的质量管理体系，全力确保在医用级塑料 (MGP) 的开发、生产和加工中满足最严格的标准。

热塑宝 M 系列是专为医疗、制药和诊断应用领域开发的化合物，该系列材料被应用于直接接触体液和血液的医疗产品。

为确保产品始终符合各项关键规定，我们实施了变更控制管理系统并积极采取有效措施，从而来保障制造商和最终客户的利益。

APPLICATION AREAS

GETTING THE JOB DONE EVERYWHERE

应用领域

TPE 无处不在, 放心, 可靠



MEDICAL ENGINEERING 医学工程

- Dental technology
- Hoses
- Lids / Closures
- Membranes
- Needle shields
- Plunger seals
- Valves
- 牙科技术
- 软管
- 盖子/闭合产品
- 薄膜
- 针防护件
- 柱塞密封件
- 阀门



DIAGNOSIS 诊断

- Bellows
- Plugs and septums
- Seals / Gaskets
- Valves
- 波纹管
- 插头和隔垫
- 密封件/垫圈
- 阀门



PHARMACEUTICAL PACKAGING 药品包装

- Lids / Closures
- Plugs and septums
- Seals / Gaskets
- Springs
- Valves
- 盖子/闭合产品
- 插头和隔垫
- 密封件/垫圈
- 弹簧
- 阀门

SAFETY AND PURITY

CHOOSE THE PUREST SOLUTION

安全和纯度

我们产品方案的两大特色

Our compounds exemplify the greatest possible product purity and highest processing safety standards. TPEs from the THERMOLAST® M series are produced exclusively at our headquarters in Waldkraiburg, Germany.

- Free of latex, PVC, phthalates, and heavy metals
- Sterilizable using common methods
- Translucent or transparent
- Vegan products possible

Selected compounds comply with recognized medical standards:

- » DIN ISO 10993-4 "Haemolysis, indirect blood contact"
- » DIN ISO 10993-5 "Cytotoxicity"
- » DIN ISO 10993-10 "Intracutaneous irritation"
- » DIN ISO 10993-11 "Acute system toxicity"
- » USP Class VI Extraction tests
- » VDI 2017 Medical Grade Plastics

We'll be happy to advise you right from the start of your project to ensure the greatest possible safety.

我们的化合物属于行业中极高纯度产品，这意味着我们满足了行业加工安全的最高标准。热塑宝 M 系列的热塑性弹性体仅在德总部瓦尔德克赖堡工厂生产。

- 不含乳胶、PVC、邻苯二甲酸盐和重金属
- 可使用常规方法消毒杀菌
- 半透明或透明
- 可提供纯素产品

精心选择的成分符合广泛认可的医疗标准：

- » DIN ISO 10993-4 "溶血、间接血液接触"
- » DIN ISO 10993-5 "细胞毒性"
- » DIN ISO 10993-10 "皮内刺激"
- » DIN ISO 10993-11 "急性系统毒性"
- » USP Class VI 类 提取测试
- » VDI 2017 医用级塑料

我们热忱为您从项目初期提供咨询服务，助您保障全程安全。

DURABILITY AND FLEXIBILITY

THE TINIEST DETAILS COUNT

耐用性和灵活性

用细节向您证明

In addition to the purity of the raw materials used, THERMOLAST® M compounds also stand out through their performance characteristics:

- Adhesion to polyolefins and technical thermoplastics such as ABS/PC/PA by means of multi-component injection molding
- Durability and flexibility
- Excellent compression set characteristics
- Excellent resealing properties
- High transparency und pre-coloring options
- Injection molding and extruding possible
- Low-friction and highly elastic

We also take customer-specific materials requests to provide solutions that guarantee constant and unvarying quality. In addition, our compounds offer optimum soft-touch features.

除了原料纯度外，热塑宝 M 化合物还通过其性能特征脱颖而出：

- 可粘合聚烯烃和技术热塑性塑料，例如例如多组件注塑成型的 ABS/PC/PA
- 耐用性和灵活性
- 出色的压缩变形特性
- 优异的再密封性能
- 高透明度和预着色选项
- 非凡的注塑和挤出工艺
- 低摩擦性和高弹性

我们还可根据客户特定的材料要求提供质量稳定持久的解决方案。此外，我们的化合物具有非常出色的柔软触感。



ADVICE AND SUPPORT

GETTING IT ALL GOING

咨询和支持

全力以赴

Quality, safety, and reliability are an absolute must in medical technology. We make sure these requirements are delivered by providing continuous and individualized customer care through a unique service package.

As we specialize in high-quality TPS, you can be sure of receiving material purity and expert advice at the highest level.

Your needs are our focus:

- Constant manufacturing process recorded in the drug master file
- Guaranteed 24-month availability guarantee (Change Control Procedure)
- Purity of the raw materials through commitment by suppliers
- Separate, permanently assigned production units for THERMOLAST® M

对于医疗技术而言，质量、安全性和可靠性三要素是绝对必要的先决条件。我们通过独特的服务套餐，为客户提供持续和个性化的服务，确保满足客户独特的需求。

我们从事专业制造高品质 TPS，致力为您提供高纯度的产品和高水平的专业服务。

您的需要就是我们的使命：

- 药品管理档案中记录的持续制造流程
- 保证 24 个月可用（变更控制流程）
- 供应商承诺的原料纯度
- 为热塑宝 M 指定的独立永久生产单元



SUSTAINABILITY

ALWAYS LOOKING TO THE FUTURE

可持续发展

立足当下，着眼未来

Sustainability isn't just a buzzword at KRAIBURG TPE, it's a principle we live by. With us you are choosing a partner who takes on responsibility for the environment and society. Today and tomorrow. For example, we do not use palm oil in the materials we produce.

Our compounds are PVC-free, halogen-free and recyclable.

- Certified worldwide in accordance with ISO 14001 and ISO 9001
- Headquarters in Germany certified in accordance with ISO 50001
- EH&S management, reporting & auditing
- Systematic energy management
- Annually renewed environmental protection and occupational safety program
- Selection of raw materials suppliers based on quality and environmental impact

在凯柏胶宝®，可持续发展不仅仅是一个时下流行的概念，更是我们身体力行的原则。选择我们，您将会拥有一位对环境、对社会有责任有担当的合作伙伴，不止当下，还有未来。例如，我们生产的材料中不会使用棕榈油。

我们的化合物中不含PVC、卤素，并且可以回收利用。

- 全球所有生产基地皆符合 ISO 14001 和 ISO 9001 认证标准
- 德国总部符合 ISO 50001 认证标准
- EH&S 管理、报告和审计
- 系统的能源管理
- 每年更新环境保护和职业安全计划
- 根据质量和环境影响选择原材料供应商



TPE PORTFOLIO SERIES

MEDICAL SECTOR

TPE 产品系列

医疗应用

热塑宝 M
THERMOLAST® M

包胶材料
Adhesion Materials

MC/AD1	ABS, PC, PC/ABS
MC/AD/PA	PA
MC/HE	PP
MC/LF	PP
MC/RS	PE, PP
MC/tl	PE, PP

THERMOLAST® M | 热塑宝 M

Series 系列

MC/AD1

The MC/AD1 series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its adhesion properties to polar thermoplastics such as PC, ABS, PC/ABS. The compounds are available in translucent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

MC/AD1系列适用于基本医疗批复(如 ISO 10993-5)应用的材料解决方案。该系列具有包胶 PC、ABS 和 PC/ABS 等极性热塑性材料的特点。这类化合物为半透明,可用多种不同方式着色。这类化合物仅由专门的医疗部门生产。

Processing Method: Injection Molding | 加工方法:注塑成型

Compound Name 化合物名称	Hardness 硬度	Color 颜色	Adhesion 包胶
TMxADT	30 - 70 Shore A	Translucent 半透明	ABS, PC, PC/ABS

Typical Applications	典型应用
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- Flexible Connections
- Membranes
- Seals
- Seals for housings
- Soft touch
- Valves

- 柔性连接器
- 薄膜
- 密封件
- 机壳密封件
- 软触感
- 阀门

Material Advantages	材料属性
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- Abrasion resistance
- Adhesion to PC, ABS, PC/ABS, ASA, SAN
- Adhesion to PET and PETG
- Adhesion to PS
- Free from animal ingredients
- KRAIBURG TPE Medical Service Package
- Sterilizable (autoclave 134 °C, β - γ -radiation 2x35 kGy, EtO)
- US DMF listed

- 耐磨性
- 包胶 PC、ABS、PC/ABS、ASA、SAN
- 包胶 PET 和 PETG
- 包胶 PS
- 不含动物性成分
- 凯柏胶宝®公司医疗服务包
- 可消毒灭菌(134 °C 高压灭菌、2 x 35 kGy 伽玛辐射、环氧乙烷)
- 美国药品主控文件 (US DMF) 认证

Regulations / Approvals	法规 / 批准
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- ISO 10993-4 (Hemolysis)
- ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous irritation)
- ISO 10993-11 (Acute systemic toxicity)
- Regulation (EU) No 10/2011
- US CFR 21 FDA (raw material conformity)
- USP <88> (Biological Reactivity, Class VI)
- VDI 2017

- ISO 10993-4 (血液相容性)
- ISO 10993-5 (细胞毒性)
- ISO 10993-10 (皮内刺激)
- ISO 10993-11 (急性全身毒性)
- 欧盟法规 (EU) No 10/2011
- US CFR 21 FDA (原料符合性)
- USP <88> (Biological Reactivity, Class VI)
- VDI 2017

THERMOLAST® M | 热塑宝 M

Series 系列

MC/AD/PA

The MC/AD/PA series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its adhesion to various polyamides, such as PA6 and PA12. The compounds are available in natural colors and can be colored in a variety of ways. They are produced exclusively on a special medical unit.

MC/AD/PA系列产品所提供的材料解决方案,满足您应用领域的基本医疗认证需求,如 ISO 10993-5。该系列产品可对各种聚酰胺材料,如 PA6 和 PA12进行包胶。该化合物拥有自然色,也可提供各种不同颜色的产品。这类化合物仅由专门的医疗部门生产。

Processing Method: Injection Molding | 加工方法:注塑成型

Compound Name 化合物名称	Hardness 硬度	Color 颜色	Adhesion 包胶
TMxAPO	60 - 70 Shore A	Natural 自然色	PA

Typical Applications	典型应用
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- Flexible Connections
- Grip applications
- Seals
- Seals for plugs
- Soft touch
- Soft touch for grips, switches and mats

- 柔性连接器
- 把手应用
- 密封件
- 插头密封件
- 软触感
- 把手、开关和橡胶垫的柔软触感

Material Advantages	材料属性
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- Adhesion to PA6 and PA12
- Colorable, also in effect colors
- KRAIBURG TPE Medical Service Package
- Sterilizable (β - γ -radiation 2x35 kGy, EtO)

- 包胶 PA6 和 PA12
- 可染色,也可做特殊效果颜色
- 凯柏胶宝®公司医疗服务包
- 可消毒 (β - γ -radiation 2x35 kGy, EtO)

Regulations / Approvals	法规 / 批准
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- ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous irritation)
- Regulation (EU) No 10/2011
- US CFR 21 FDA (raw material conformity)
- VDI 2017

- ISO 10993-5 (细胞毒性)
- ISO 10993-10 (皮内刺激)
- 欧盟法规 (EU) No 10/2011
- US CFR 21 FDA (原料符合性)
- VDI 2017

THERMOLAST® M | 热塑宝 M

Series 系列	The MC/HE series is your material solution for applications requiring basic medical approvals such as ISO10993-5. The series is characterized by its elasticity at high hardness. The compounds are transparent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.
MC/HE	MC/HE 系列适用于基本医疗批复（如 ISO 10993-5）应用的材料解决方案。该系列材料在高硬度时具有出色的弹性。产品颜色为透明，可用多种不同方式着色。这类化合物仅由专门的医疗部门生产。

Processing Method : Injection Molding | **加工方法** : 注塑成型

Compound Name	化合物名称	Hardness	硬度	Color	颜色	Adhesion	包胶
TMxHET		40 – 50 Shore D		Transparent	透明	PP	
Typical Applications		典型应用					
<ul style="list-style-type: none">Drip chamberLuer lockSqueeze bottles		<ul style="list-style-type: none">滴注器鲁尔锁紧头挤压瓶					
Material Advantages		材料属性					
<ul style="list-style-type: none">Adhesion to PPElasticityFree from animal ingredientsKRAIBURG TPE Medical Service PackageSterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)StiffnessUS DMF listedWeldable (Ultrasonic)		<ul style="list-style-type: none">包胶PP弹性不含动物性成分凯柏胶宝®公司医疗服务包可消毒灭菌 (134 °C 高压灭菌、2 x 35 kGy 伽玛辐射、环氧乙烷)刚性美国药品主控文件 (US DMF) 认证可焊接 (超声波)					
Regulations / Approvals		法规 / 批准					
<ul style="list-style-type: none">ISO 10993-4 (Hemolysis)ISO 10993-5 (Cytotoxicity)ISO 10993-10 (Intracutaneous irritation)ISO 10993-11 (Acute systemic toxicity)Regulation (EU) No 10/2011US CFR 21 FDA (raw material conformity)US FDA CFR 21USP <88> (Biological Reactivity, Class VI)VDI 2017		<ul style="list-style-type: none">ISO 10993-4 (血液相容性)ISO 10993-5 (细胞毒性)ISO 10993-10 (皮内刺激)ISO 10993-11 (急性全身毒性)欧盟法规 (EU) No 10/2011US CFR 21 FDA (原料符合性)US FDA CFR 21USP <88> (Biological Reactivity, Class VI)VDI 2017					

THERMOLAST® M | 热塑宝 M

Series 系列	The MC/LF series is your material solution for applications requiring basic medical approvals such as ISO10993-5. The series convinces by a low coefficient of friction. The compounds are translucent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.
MC/LF	MC/LF 系列适用于基本医疗批复（如 ISO 10993-5）应用的材料解决方案。该系列拥有极低的摩擦系数。产品颜色为半透明，可用多种不同方式着色。这类化合物仅由专门的医疗部门生产。

Processing Method : Extrusion, Injection Molding | **加工方法** : 挤塑, 注塑成型

Compound Name	化合物名称	Hardness	硬度	Color	颜色	Adhesion	包胶
TMxLFT		30 – 90 Shore A		Translucent	半透明	PP	
Typical Applications		典型应用					
<ul style="list-style-type: none">Mechanical componentsSealsSyringe gaskets		<ul style="list-style-type: none">机械部件密封件注射器密封圈					
Material Advantages		材料属性					
<ul style="list-style-type: none">Abrasion resistanceAdhesion to PPKRAIBURG TPE Medical Service PackageLow surface frictionOptimized mechanical propertiesScratch resistanceSterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)US DMF listed		<ul style="list-style-type: none">耐磨性包胶PP凯柏胶宝®公司医疗服务包低表面摩擦力优异的机械特性耐刮擦可消毒灭菌 (134 °C 高压灭菌、2 x 35 kGy 伽玛辐射、环氧乙烷)美国药品主控文件 (US DMF) 认证					
Regulations / Approvals		法规 / 批准					
<ul style="list-style-type: none">ISO 10993-4 (Hemolysis)ISO 10993-5 (Cytotoxicity)ISO 10993-10 (Intracutaneous irritation)ISO 10993-11 (Acute systemic toxicity)Regulation (EU) No 10/2011US CFR 21 FDA (raw material conformity)US FDA CFR 21USP <88> (Biological Reactivity, Class VI)VDI 2017		<ul style="list-style-type: none">ISO 10993-4 (血液相容性)ISO 10993-5 (细胞毒性)ISO 10993-10 (皮内刺激)ISO 10993-11 (急性全身毒性)欧盟法规 (EU) No 10/2011US CFR 21 FDA (原料符合性)US FDA CFR 21USP <88> (Biological Reactivity, Class VI)VDI 2017					

THERMOLAST® M | 热塑宝 M

Series 系列	The MC/RS series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its resealing properties. The compounds are translucent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.
MC/RS	MC/RS 系列是用于基本医疗批复（如 ISO 10993-5）应用的材料解决方案。该系列材料具有出色的再密封特性。产品颜色为半透明，可用多种不同方式着色。这类化合物仅由专门的医疗部门生产。

Processing Method : Extrusion, Injection Molding | **加工方法** : 挤塑, 注塑成型

Compound Name	化合物名称	Hardness	硬度	Color	颜色	Adhesion	包胶
TMxRST		30 – 40 Shore A		Translucent	半透明	PE, PP	
Typical Applications		典型应用					
<ul style="list-style-type: none">ClosuresInfusion stoppersMembranes		<ul style="list-style-type: none">输液瓶塞薄膜封口					
Material Advantages		材料属性					
<ul style="list-style-type: none">Adhesion to PP, PEFree from animal ingredientsKRAIBURG TPE Medical Service PackageOptimized compression setResealingSterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)US DMF listedWeldable (Ultrasonic)		<ul style="list-style-type: none">包胶 PP, PE不含动物性成分凯柏胶宝®公司医疗服务包出色的压缩形变特性再密封可消毒灭菌 (134 °C 高压灭菌、2 x 35 kGy 伽玛辐射、环氧乙烷)美国药品主控文件 (US DMF) 认证可焊接 (超声波)					
Regulations / Approvals		法规 / 批准					
<ul style="list-style-type: none">ISO 10993-5 (Cytotoxicity)VDI 2017		<ul style="list-style-type: none">ISO 10993-5 (细胞毒性)VDI 2017					

THERMOLAST® M | 热塑宝 M

Series 系列	The MC/tl series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The compounds are available in translucent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.
MC/tl	MC/tl 系列适用于基本医疗批复（如 ISO 10993-5）应用的材料解决方案。这类化合物为半透明，可用多种不同方式着色。这类化合物仅由专门的医疗部门生产。

Processing Method : Extrusion, Injection Molding | **加工方法** : 挤塑, 注塑成型

Compound Name	化合物名称	Hardness	硬度	Color	颜色	Adhesion	包胶
TMxMED		30 – 90 Shore A		Translucent	半透明	PE, PP	
Typical Applications		典型应用					
<ul style="list-style-type: none">Flexible ConnectionsMouthpiecesSealsSoft touchValves		<ul style="list-style-type: none">柔性连接器烟嘴密封件软触感阀门					
Material Advantages		材料属性					
<ul style="list-style-type: none">Abrasion resistanceAdhesion to PP, PEFree from animal ingredientsKRAIBURG TPE Medical Service PackageOptimized compression setSterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)US DMF listedWeldable (Ultrasonic)		<ul style="list-style-type: none">耐磨性包胶 PP, PE不含动物性成分凯柏胶宝®公司医疗服务包出色的压缩形变特性可消毒灭菌 (134 °C 高压灭菌、2 x 35 kGy 伽玛辐射、环氧乙烷)美国药品主控文件 (US DMF) 认证可焊接 (超声波)					
Regulations / Approvals		法规 / 批准					
<ul style="list-style-type: none">ISO 10993-4 (Hemolysis)ISO 10993-5 (Cytotoxicity)ISO 10993-10 (Intracutaneous irritation)ISO 10993-11 (Acute systemic toxicity)USP <88> (Biological Reactivity, Class VI)VDI 2017		<ul style="list-style-type: none">ISO 10993-4 (血液相容性)ISO 10993-5 (细胞毒性)ISO 10993-10 (皮内刺激)ISO 10993-11 (急性全身毒性)USP <88> (Biological Reactivity, Class VI)VDI 2017					



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