



**MEDICAL**



**SAFETY THAT IS CERTAIN  
TO IMPRESS**

# OUR COMPANY

## BENEFITS IN ALL SHAPES AND SIZES

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 the challenges you face with you and support you at all times anywhere in the world.







# THE MARKET

## MAKE THE SAFE CHOICE

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

That is 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.

# APPLICATION AREAS

## GETTING THE JOB DONE EVERYWHERE

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### MEDICAL ENGINEERING

- Dental technology
- Hoses
- Lids/Closures
- Membranes
- Needle shields
- Plunger seals
- Valves



### DIAGNOSIS

- Bellows
- Plugs and septums
- Seals/Gaskets
- Valves



### PHARMACEUTICAL PACKAGING

- Lids/Closures
- Plugs and septums
- Seals/Gaskets
- Springs
- Valves



A close-up photograph showing several blue, textured strips of thermoplastic elastomer (TPE) material. These strips are arranged in a curved, overlapping pattern. Between the strips, there is a layer of small, white, spherical granules, likely TPE powder or granules. The lighting is bright, highlighting the texture of the strips and the uniformity of the granules.

# SAFETY AND PURITY

## CHOOSE THE PUREST SOLUTION

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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 from animal ingredients
- Free of latex, PVC, phthalates, and heavy metals
- Sterilizable using common methods
- Translucent or transparent

### **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 injection"
- » DIN ISO 10993-11 "Acute system toxicity"
- » USP Class VI Extraction tests
- » VDI 2017 Medical Grade Plastics

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





# DURABILITY AND FLEXIBILITY

THE TINIEST DETAILS COUNT

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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 or 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.





# ADVICE AND SUPPORT

## GETTING IT ALL GOING

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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
- 24-month availability guarantee (Change Control Procedure)
- Purity of the raw materials through commitment by suppliers
- Separate, permanently assigned production units for THERMOLAST® M





# SUSTAINABILITY

ALWAYS LOOKING TO THE FUTURE

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## EXCELLENCE BY TRANSPARENCY

**We rely on certified processes and established standards**

KRAIBURG TPE acts and operates in accordance with recognized standards. **These are:**

- **Integrated quality, environment and energy management systems**
- **Certified GRS standard for products produced in Malaysia**
- **Product Carbon Footprint of KRAIBURG TPE-Compounds**
- **Climate targets based on the guidelines of the Sciences Based Target Initiative (SBTi):** Starting from the base year of 2021, the company's scope 1 and scope 2 CO<sub>2</sub>e emissions are to be reduced by 46.2 percent by 2031, scope 3 CO<sub>2</sub>e by 27.5 percent.
- **ISCC PLUS certification** available for many products in the EMEA sales region
- **Carbon Disclosure Project (CDP)** rating since 2020
- **EcoVadis:** The platform classifies the sustainability of companies in holistic ratings. Our commitment to sustainability at our locations has been awarded "Gold" and "Silver" in the past.





# TPE PORTFOLIO SERIES

## MEDICAL SECTOR

THERMOLAST® M	Adhesion Materials	Page
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### THERMOLAST® M

#### Series MC

The MC series is your material solution for applications requiring basic medical approvals such as ISO 10993-5 and food regulations. The compounds are available in translucent colors and can be colored in many different ways. They are produced exclusively on a special medical unit.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxMEP	30 – 90 Shore A	Translucent	PE, PP

#### Typical Applications

- Flexible Connections
- Pharmaceutical packaging
- Seals
- Valves

#### Material Advantages

- Adhesion to PE, PP
- Free from animal ingredients
- KRAIBURG TPE Medical Service Package
- Optimized compression set
- Sterilizable (autoclave 134 °C,  $\beta$ -/y-radiation 2x35 kGy, EtO)
- US DMF listed

#### Regulations / Approvals

- GB4806.7-2023
- Compatible for HDPE Recycling certified by Cyclos HTP
- Compatible for PP Recycling certified by Cyclos HTP
- ISO 10993-4 (Hemolysis)
- ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous injection)
- ISO 10993-11 (Acute systemic toxicity)
- ISO8871-1 (Part 1: Extractables in aqueous autoclavates)
- Regulation (EU) No 10/2011
- US FDA CFR 21
- VDI 2017

### THERMOLAST® M

#### Series 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 ABS, PC and PET/PETG. The compounds are available in natural colors and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

Processing Method : Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxADX-NTRL	50 – 70 Shore A	Natural	ABS, PC, PET/PETG

#### Typical Applications

- Flexible Connections
- Membranes
- Seals
- Soft touch application (e.g. handles or push buttons)
- Valves

#### Material Advantages

- Adhesion to ABS, ASA, PC, PC/ABS, SAN
- Adhesion to PET and PETG
- Adhesion to PS
- Free from animal ingredients
- ISCC PLUS ready (mass balance approach)
- KRAIBURG TPE Medical Service Package
- Soft touch surface
- Sterilizable (autoclave 134 °C,  $\beta$ -/y-radiation 2x35 kGy, EtO)

#### Regulations / Approvals

- ISO 10993-4 (Hemolysis)
- ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous injection)
- ISO 10993-11 (Acute systemic toxicity)
- USP <88> (Biological Reactivity, Class VI)
- VDI 2017



THERMOLAST® M

Series  
MC/HE

The MC/HE series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its elasticity and transparency at high hardness plus its adhesion to PP. The compounds are transparent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

Processing Method : Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxHET	40 – 50 Shore D	Transparent	PP

Typical Applications

- Closure caps
  - Drip chamber
- Luer lock
  - Squeeze bottles

Material Advantages

- Adhesion to PP
  - Elasticity
  - Free from animal ingredients
  - ISCC PLUS ready (mass balance approach)
  - KRAIBURG TPE Medical Service Package
- Sterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)
  - Stiffness
  - Transparency
  - US DMF listed
  - Weldable (Ultrasonic)

Regulations / Approvals

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

THERMOLAST® M

Series  
MC/LF

The MC/LF series is your material solution for applications requiring basic medical approvals such as ISO 10993-5. 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.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxLFT	30 – 90 Shore A	Translucent	PP

Typical Applications

- Mechanical components
  - Membranes
  - Seals
- Soft touch application (e.g. handle or push button)
  - Syringe gaskets

Material Advantages

- Abrasion resistance
  - Adhesion to PP
  - ISCC PLUS ready (mass balance approach)
  - KRAIBURG TPE Medical Service Package
  - Low surface friction
- Optimized mechanical properties
  - Scratch resistance
  - Smooth touch
  - Sterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)
  - US DMF listed

Regulations / Approvals

- Compatible for HDPE Recycling certified by Cyclos HTP
  - Compatible for PP Recycling certified by Cyclos HTP
  - ISO 10993-4 (Hemolysis)
  - ISO 10993-5 (Cytotoxicity)
  - ISO 10993-10 (Intracutaneous injection)
- ISO 10993-11 (Acute systemic toxicity)
  - Regulation (EU) No 10/2011
  - US FDA CFR 21 (raw material conformity)
  - USP <88> (Biological Reactivity, Class VI)
  - VDI 2017

THERMOLAST® M

Series  
MC/RS

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 and its adhesion to PP and PE. The compounds are translucent and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxRST	30 – 40 Shore A	Translucent	PE, PP

Typical Applications

- Closures
  - Infusion stoppers
- Membranes

Material Advantages

- Adhesion to PE, PP
  - Free from animal ingredients
  - ISCC PLUS ready (mass balance approach)
  - KRAIBURG TPE Medical Service Package
  - Optimized compression set
- Resealing
  - Sterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)
  - US DMF listed
  - Weldable (Ultrasonic)

Regulations / Approvals

- Compatible for HDPE Recycling certified by Cyclos HTP
  - Compatible for PP Recycling certified by Cyclos HTP
- ISO 10993-5 (Cytotoxicity)
  - VDI 2017

THERMOLAST® M

Series  
MC/tl

The MC/tl series is your material solution for various applications requiring basic medical approvals such as ISO 10993-5. The series is characterized by its adhesion to PP and PE. The compounds are available in translucent colors and can be colored in many different ways. The compounds are produced exclusively on a special medical unit.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
TMxMED	30 – 90 Shore A	Translucent	PE, PP

Typical Applications

- Flexible Connections
  - Membranes
  - Mouthpieces
- Seals
  - Soft touch application (e.g. handle or push button)
  - Valves

Material Advantages

- Adhesion to PE, PP
  - Free from animal ingredients
  - ISCC PLUS ready (mass balance approach)
  - KRAIBURG TPE Medical Service Package
- Optimized compression set
  - Sterilizable (autoclave 134 °C, β-/γ-radiation 2x35 kGy, EtO)
  - US DMF listed
  - Weldable (Ultrasonic)

Regulations / Approvals

- Compatible for HDPE Recycling certified by Cyclos HTP
  - Compatible for PP Recycling certified by Cyclos HTP
  - ISO 10993-4 (Hemolysis)
  - ISO 10993-5 (Cytotoxicity)
- ISO 10993-10 (Intracutaneous injection)
  - ISO 10993-11 (Acute systemic toxicity)
  - USP <88> (Biological Reactivity, Class VI)
  - VDI 2017



THERMOLAST® H

Series  
HC/AD1/AP

The HC/AD1/AP series is your material solutions exclusively designed for healthcare and medical device applications in Asia Pacific. These compounds comply with ISO 10993-5 and GB/T 16886.5. They are characterized by their adhesion properties to polar thermoplastics such as PC, ABS, and PETG and are available in natural colors.

Processing Method : Injection Molding

Compound Name	Hardness	Color	Adhesion
THxPGM-NTRL	30 – 80 Shore A	Natural	ABS, PC, PETG

Typical Applications	<ul style="list-style-type: none"><li>Flexible Connections</li><li>Function and design elements</li><li>Membranes</li></ul> <ul style="list-style-type: none"><li>Seals</li><li>Soft touch for grips, switches and mats</li><li>Valves</li></ul>
Material Advantages	<ul style="list-style-type: none"><li>Adhesion to ABS, ASA, PC, PC/ABS, SAN</li><li>Adhesion to PET and PETG</li><li>Adhesion to PS</li><li>Colorable</li></ul> <ul style="list-style-type: none"><li>Free from animal ingredients</li><li>Optimized mechanical properties</li><li>Soft touch surface</li><li>Sterilizable</li></ul>

Regulations / Approvals	<ul style="list-style-type: none"><li>GB/T 16886.5 (Cytotoxicity)</li><li>ISO 10993-5 (Cytotoxicity)</li></ul> <ul style="list-style-type: none"><li>Regulation (EU) No 10/2011</li><li>US FDA CFR 21 (raw material conformity)</li></ul>
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THERMOLAST® H

Series  
HC/AP

The HC/AP series is a material solution designed exclusively for the healthcare and medical device market in Asia Pacific. The compounds comply with the ISO 10993-5, GB/T 16886.5 standards, as well as various global food contact and relevant medical standards. These compounds are available in a translucent color and can also be colored in a variety of colors.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
THxOGM-LCNT	30 – 90 Shore A	Translucent	PE, PP

Typical Applications	<ul style="list-style-type: none"><li>Closures</li><li>Flexible connections</li><li>Function and design elements</li></ul> <ul style="list-style-type: none"><li>Mouthpieces</li><li>Seals</li></ul>
Material Advantages	<ul style="list-style-type: none"><li>Adhesion to PE, PP</li><li>Colorable</li><li>Free from animal ingredients</li></ul> <ul style="list-style-type: none"><li>Optimized compression set</li><li>Sterilizable (autoclave 121 °C, EtO)</li></ul>

Regulations / Approvals	<ul style="list-style-type: none"><li>GB4806.7-2023</li><li>GB/T 16886.5 (Cytotoxicity)</li><li>ISO 10993-5 (Cytotoxicity)</li></ul> <ul style="list-style-type: none"><li>Regulation (EU) No 10/2011</li><li>US FDA CFR 21</li></ul>
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THERMOLAST® H

Series  
HC/RS/AP

The HC/RS/AP series is your material solution designed exclusively for healthcare and medical resealing applications in Asia Pacific. The compounds comply with the ISO 10993-5, GB/T 16886.5 standards, as well as various global food contact and relevant medical standards. They are also tested according to DIN ISO 15759. These compounds are available in translucent and can also be colored in a variety of colors.

Processing Method : Extrusion, Injection Molding

Compound Name	Hardness	Color	Adhesion
THxOHG-LCNT	30 – 40 Shore A	Translucent	PE, PP

Typical Applications	<ul style="list-style-type: none"><li>Caps</li><li>Closures</li></ul> <ul style="list-style-type: none"><li>Membrane</li><li>Plugs</li></ul>
Material Advantages	<ul style="list-style-type: none"><li>Adhesion to PE, PP</li><li>Colorable</li><li>Low density</li></ul> <ul style="list-style-type: none"><li>Resealing</li><li>Sterilizable</li></ul>

Regulations / Approvals	<ul style="list-style-type: none"><li>GB4806.7-2023</li><li>GB/T 16886.5 (Cytotoxicity)</li><li>ISO 10993-5 (Cytotoxicity)</li></ul> <ul style="list-style-type: none"><li>Regulation (EU) No 10/2011</li><li>US FDA CFR 21</li></ul>
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