

## Press release

KRAIBURG TPE presents a new materials solution for the medical market

Waldkraiburg, November 2020

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KRAIBURG TPE presents a new materials solution for pharmaceutical packaging

### Safely packed and well prepared

**Primary packaging for solid and liquid drugs, as well as many other products, will benefit from the latest addition to the THERMOLAST® M series. But KRAIBURG TPE is also keeping abreast with the times organizationally: the service package that comes with the product ensures customers are always perfectly prepared for future rules and regulations.**

Patients and medical professionals usually remember the outer packaging of drugs, due to the variety of the design options. It's often easier and less costly to adjust the outer packaging than to adjust the primary packaging. However, the primary packaging is critical for the patient, as it protects the drug against unwanted environmental influences, alteration and contamination. The new compounds from KRAIBURG TPE have been specifically developed for these uses – for solid and liquid drugs, as well as sprays. Applications that benefit from this new series of materials include seals and gaskets, valves and flexible joints.

The compounds in this new segment of the THERMOLAST® M series have been specially developed for applications that require basic medical approval and have to meet food regulations. In addition, extraction tests in accordance with ISO 8871-1 have been successfully performed; all of the raw materials tested are certified under Regulation (EU) No. 10/2011 and US CFR 21 (FDA) standards. The biocompatibility of the materials series is certified in accordance with ISO 10993-4, -5, -10 and -11, as well as with ISO 8871-1 for parenterals and for devices for pharmaceutical use. The materials also meet the requirements of USP661.1 (plastic materials of construction) as well as of USP661.2 (plastics packaging systems for pharmaceutical use).

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Overview of important additional materials properties:

- The translucent TPEs can be colored
- Excellent mechanical properties
- Low compression set
- Sterilizable: Autoclave 121 °C and 134 °C,  $\beta/\gamma$  radiation 2x35 kGy, EtO
- Free of PVC, silicone and latex
- Free of animal ingredients

Another important criterion: Customers will benefit from the unique service package for medical-grade products, which provides advantages in view of the Medical Device Regulation that will be coming into effect from early summer 2021.

- Consistent production procedure; meets all requirements for a full-fledged medical-grade plastic in accordance with the VDI 2017 technical rule
- Guaranteed 24-month supply security
- Purity of the raw materials through commitment by suppliers
- Separate, permanently assigned production units for THERMOLAST® M

“With many years of experience and the approvals we hold, we are in a good position to compete in the pharmaceutical packaging market. But the human aspect also plays an import part, as customers can rely on our unique medical service package, with consistent materials supply as well as consistent quality and ingredients,” emphasizes Eugen Andert, Product Development Engineer at KRAIBURG TPE.

The product is now available and can be ordered from your familiar contact partner or distributor.

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**Image:** Primary packaging for solid and liquid drugs – as well as many other products – benefits from the latest addition to the THERMOLAST® M series.  
(Image: KRAIBURG TPE)

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### **About KRAIBURG TPE**

KRAIBURG TPE ([www.kraiburg-tpe.com](http://www.kraiburg-tpe.com)) is a global manufacturer of thermoplastic elastomers. From its beginning in 2001 as subsidiary of the historical KRAIBURG Group founded in 1947, KRAIBURG TPE has pioneered in TPE compounds, today being the competence leader in this industry. With production sites in Germany, the US, and Malaysia the company offers a broad range of compounds for applications in the automotive, industrial, consumer, and for the strictly regulated medical sectors. The established THERMOLAST®, COPEC®, HIPEX®, and For Tec E® product lines are processed by injection molding or extrusion and provide numerous processing and product design advantages to manufacturers. KRAIBURG TPE features innovative capabilities as well as true global customer orientation, customized product solutions and reliable service. The company is certified to ISO 50001 at its headquarters in Germany and holds ISO 9001 and ISO 14001 certifications at all global sites. In 2019, KRAIBURG TPE, with over 640 worldwide employees, generated sales of 190 million euros.

You can download this press release and relevant illustrations from [www.PressReleaseFinder.com](http://www.PressReleaseFinder.com).

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