

Press release

The world's first MGP-certified TPE series with adhesion to PA for medical devices

Waldkraiburg, October 2019

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KRAIBURG TPE to introduce the world's first VDI 2017-compliant THERMOLAST® M compounds for TPE/PA composite applications

Fully certified and sterilizable compounds compatible with PA

With its new MC/AD/PA THERMOLAST® M series, KRAIBURG TPE launches the first thermoplastic elastomers that not only hold certifications for healthcare applications in accordance with EU and FDA standards but can also be combined directly with polyamides.

As international regulations for medical-grade plastics (MGPs) have become more and more strict, manufacturers of products for medical devices and healthcare are increasingly looking for opportunities to strengthen their competitive edge by solutions that both comply with the regulations and are aesthetically pleasing. A representative example is the manufacture of multicomponent applications that saves mounting time by combining a "hard" polymer with a "soft-touch" thermoplastic elastomer (TPE) using direct injection molding (without bonding agents). The MGP-compliant TPE compounds that have been available in the market so far do not provide adhesion to polyamides (PA) and thus cannot be used for many sophisticated applications.

KRAIBURG TPE's new MC/AD/PA THERMOLAST® M series closes this gap. "We are looking forward to introducing the world's first TPEs for medical applications in composites with polyamides – including transparent PA12 – to the industry at K 2019," says Oliver Kluge, Business Unit Manager Medical Applications at KRAIBURG TPE. "The compounds are fully certified and suitable for a variety of attractive medical devices, including those used for in vitro diagnostics.

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The compounds of the new TPE series meet the recently adopted VDI 2017 guideline that regulates the criteria for MGP-compliant materials – from basic requirements to formulation consistency and modification management. They comply with the Commission Regulation (EU) No. 10/2011 and the Code of Federal Regulations Title 21 (21CFR) of the U.S. Food and Drug Administration (FDA).

The new TPEs also meet the requirements for human compatibility in accordance with the specifications of the ISO 10993-5 and 10993-11 standards. All types can be sterilized using beta or gamma radiation, or ethylene oxide (EtO). They also comply with Directive 2011/65/EU on the restriction of the use of certain hazardous substances (RoHS) as well as Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH).

Like all THERMOLAST® M products, the MC/AD/PA compounds are free of latex, PVC, and phthalates, and they are produced without the use of heavy metals. KRAIBURG TPE manufactures the newly developed materials exclusively on specially approved production lines. Quality assurance extends through to full traceability of raw materials on the suppliers' side. Types with a hardness range between 60 and 70 Shore A are currently available. They provide smooth and velvety surfaces with a pleasantly soft touch featuring excellent resistance to scratches, wear, and sebum (lipids secreted to the skin's surface).

KRAIBURG TPE will present its new MC/AD/PA THERMOLAST® M series during K 2019 in hall 6 at booth C58-4.

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The world's first MGP-certified TPE series with adhesion to polyamide is perfectly suitable for medical devices. (Image: © 2019 KRAIBURG TPE)