EMS Products for Medical Applications

The requirements for plastic materials in medical devices are governed by various standards and regulations to ensure the safety, efficacy, and quality of these devices. The specific requirements may vary depending on the type of medical device, its intended use, and the regulatory jurisdiction. Safety for patients and users is the primary requirement for medical devices.

Medical Grade Plastics are materials that meet specific standards and requirements to ensure their suitability for use in medical and healthcare applications. These plastic materials are designed to be safe, reliable, and compatible with the human body. Various medical devices and equipment, ranging from simple tools to complex implants, utilize Medical Grade Plastics due to their unique characteristics.

However, the use of Medical Grade Plastics does not explicitly absolve the manufacturer of medical devices, including in-vitro diagnostics and primary pharmaceutical packaging, from the statutory requirements and obligations relating to testing, due diligence, and liability, as governed by the relevant directives and regulations.

EMS products meet key aspects and requirements for Medical Grade Plastics

Biocompatibility: Plastics used in medical applications must often be biocompatible, meaning they should not cause harmful effects when in contact with living tissues. Biocompatibility testing evaluates the potential for irritation, sensitization, and toxicity. The US Pharmacopeia class VI and ISO 10993 test reports of many EMS grades support the biological safety assessment of the medical device.

Chemical Composition: EMS controls carefully the chemical composition of the respective plastic material to ensure that it meets specific standards and does not contain leachable or extractable substances that could be harmful in a medical context. An example are Bisphenol substances like BPA and BPS, which are not contained in our products.

Resistance to Chemicals: Medical devices and components are often exposed to various chemicals, including disinfectants and cleaning agents. The plastic materials must be resistant against degradation when exposed to these substances. In particular transparent or amorphous plastic materials must also be resistant against stress cracking when exposed to chemicals. The extremely broad resistance to disinfectants, other aggressive liquids, and various drug formulations and is one of the key strengths of Grilamid TR especially compared to Polycarbonate or Polyester grades.

Sterilization Compatibility: Medical devices need to be safe and are therefore often sterilized to prevent infections. Plastic materials must be able to withstand sterilization methods such as autoclaving, ethylene oxide (EtO) sterilization, gamma radiation, or other approved methods without compromising their properties. EMS offers with Grilamid TR HT 200 a transparent material that can be repeatedly steam sterilized at 136°C without losing its performance. All our grades can be sterilized via ethylene oxide or irradiation (i.e. gamma radiation up ≤ 50 kGy).

Mechanical Properties: The mechanical properties of plastic materials, such as strength, flexibility, and dimensional stability, must meet the requirements for the intended use of the medical device. This includes considerations for long-term durability and flexural fatigue resistance, which is tested in our laboratories.

Transparency and Radiopacity: Depending on the application, the plastic materials may need to be transparent for visual monitoring or radiopaque for better visibility in imaging techniques such as X-rays. Various products that EMS manufactures offer high and up to crystal clear transparencies even in the UV wavelength range.

Regulatory Compliance: Plastic materials for medical devices must comply with relevant regulatory standards and guidelines, such as those set by health authorities like the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), or other regulatory bodies in different countries. EMS monitors requirements like REACH/SVHC and RoHS continuously on its impact, and we inform our customers about changes in regulatory status if required.

Traceability and Consistency: Tracking and documenting all raw materials used in the production as well as tight quality control is a matter of course within the EMS quality system to ensure traceability and accountability.

Change Management:
Individual customer agreements assure constancy of formulation, and written notifications in case of possible changes of formulation or production location. EMS informs customers ahead of time about modifications of product specification that change product performance or processing behaviour.
Redundant production lines and the possibility to produce at alternative EMS production locations contribute to maintaining delivery reliability.

EMS Risk Assessment
EMS authorizes the use of its products in Medical Device applications, including in-vitro diagnostic and primary pharmaceutical packaging based on a risk assessment. Prohibited applications are those with times of contact of >72 hours for implants or contact with inner body fluids or open tissue or critical components in medical devices that support or sustain human life.
Packaging for medical ingredients that are ingested through the stomach, or other medical applications are not subject to risk assessment by EMS.