

**Medanco BV**

**Medical Device Regulation (MDR)** refers to the European Union regulation (EU) 2017/745, which governs the design, manufacturing, and marketing of medical devices within the EU. This regulation sets stringent requirements for the safety, performance, and quality of medical devices, including those produced using plastic injection moulding. Understanding how the MDR applies to plastic injection moulding is crucial for manufacturers involved in producing medical devices.

Here's how the **MDR** and **plastic/TPE injection moulding** are linked:

### 1. Compliance with MDR for Medical Device Manufacturing

- **Risk Classification:** Under the MDR, medical devices are categorized based on their risk level (e.g., Class I, IIa, IIb, and III). The level of regulatory scrutiny depends on the classification, with higher-risk devices requiring more rigorous testing and documentation.
- **Material Safety:** Plastic injection moulded parts used in medical devices must meet strict standards for material safety. Materials must be biocompatible, non-toxic, and comply with regulatory standards such as ISO 10993 (for biocompatibility).
- **Traceability and Documentation:** Manufacturers must maintain detailed documentation to ensure full traceability of the materials, processes, and manufacturing steps involved in creating the device. This includes raw material certifications, production batch records, and inspection reports.
- **Sterilization:** Many medical devices made from plastic injection moulding must be sterilizable. The moulding process must consider whether the materials used can withstand the sterilization methods, such as autoclaving or gamma radiation. Medanco knows the companies which can provide these services and can also manage this for the customer.

### 2. Quality Management System (QMS)

- **ISO 13485 Certification:** Manufacturers of medical devices using plastic injection moulding must adhere to ISO 13485, which outlines quality management system requirements specific to medical device production. This standard ensures that products consistently meet customer and regulatory requirements.
- **Process Validation:** Under the MDR, manufacturers must validate their production processes to demonstrate that they consistently produce products meeting their specifications. This includes mould design, plastic injection parameters, and material handling.

### 3. Design and Manufacturing Considerations for Medical Devices

- **Precise Control Over Injection Moulding:** The injection moulding process for medical devices needs to be highly controlled to meet the required standards. This involves managing parameters such as temperature, pressure, cycle time, and cooling rates to ensure that the final product is consistent and meets regulatory standards.
- **Material Selection:** The choice of materials is critical in plastic injection moulding for medical devices. Medical-grade plastics such as polypropylene (PP), polycarbonate (PC), and polyethylene (PE) are often used. These materials must meet MDR's biocompatibility and performance requirements. Biocompatibility refers to USP Class VI and ISO10993 materials.



- **Surface Finish and Cleanliness:** The moulded parts must meet strict surface finish requirements. Cleanliness is also a priority in medical device manufacturing, as contamination can impact both safety and performance.

#### 4. Post-Production Requirements

- **Labeling and Instructions for Use:** The MDR specifies that all medical devices must have clear labeling, including the name of the manufacturer, instructions for use, and specific warnings related to the device's application. This labeling must be included on the moulded parts or their packaging. Medanco can manage all these requirements in case end-user packaging.
- **Post-Market Surveillance:** Once a medical device is on the market, manufacturers are required to monitor its performance. This includes tracking any adverse events and taking corrective actions if needed. This extends to the parts produced via injection moulding, requiring full traceability and reporting. This is the responsibility of the legal manufacturer.

#### 5. Risk Management

- **Risk Assessment:** As part of the MDR, manufacturers must conduct thorough risk assessments throughout the design and manufacturing process. Plastic injection moulded parts used in medical devices must undergo risk analysis to evaluate the potential for failure and ensure that the devices are safe for their intended use.
- **Design Controls:** Injection moulding must incorporate design controls to address any identified risks, including failures that could occur due to material properties, moulding defects, or performance issues.

#### 6. Clinical Evaluation

- **Clinical Data Requirements:** For some medical devices, the MDR requires clinical evaluation to demonstrate the safety and effectiveness of the device. For injection-moulded medical devices, clinical data can be used to prove the reliability and performance of the plastic materials used. Medanco can support and manage these requirements if the customer wants us to.

#### Conclusion

When plastic injection moulding is used for medical devices, manufacturers must ensure full compliance with the **Medical Device Regulation (MDR)**. This involves selecting biocompatible materials, validating the moulding process, maintaining detailed documentation, and ensuring that the final product meets all safety and performance requirements. Additionally, manufacturers must follow ISO 13485 standards, maintain a rigorous quality management system, and adhere to post-market surveillance obligations to ensure continued compliance and safety.

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