Saint-Gobain
Life Sciences – Medical

Process Validation
Medical Molded Component

Consistent and Controlled

Saint-Gobain's process validation package is all-encompassing from process creation to first article inspections through final process qualification.

- **Preliminary Assessment**
  - Initiate Risk Assessment (in accordance with ISO 13485)
    - Part and Process Assessment
    - Design for Manufacturability (DFM)
  - In-House Tool Design/Build
- **Installation/Operational Qualification (IOQ)**
  - Mold Shakedown
  - Hi/Low Limit Testing
  - Design of Experiments (DoE) on Key Process Parameters
  - CpK Analysis on Print Inspection Dimensions
  - Visual Sampling
  - First Article Inspection & Report
  - Final Report
- **Process Qualification (PQ)**
  - Nominal Process Run(s)
  - Additional Capability Analysis
  - Visual Sampling
  - Final Report

To find out more about how Saint-Gobain can meet your medical manufacturing needs, contact us at medical.saint-gobain.com/contact us

Vistit us at: medical.saint-gobain.com

FLS 5296-0322-SGM

Customizable

Saint-Gobain's engineering and quality teams work directly with your team to customize our standard protocols to meet your requirements.

Compliant

Saint-Gobain can meet 21 CFR 820 requirements when required for finished devices contract-manufactured by Saint-Gobain.

Important: "Please refer to our Medical Products Disclaimer at www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer.

Saint-Gobain's medical products offer covers:

- Medical Components [21 CFR 820.3(c)], intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; Medical Components are intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)].
- Finished Devices [21CFR820.3(l)] made on behalf of medical device manufacturers [21 CFR 807.20(a)(2)] under contract-manufacturing agreement. In accordance with the United States' jurisdiction, Saint-Gobain complies with the FDA's requirements for contract manufacturers of finished devices.

Caution: For manufacturing, processing or repacking."

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain warrants this product to be free of defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof.

SAINT-GOBAIN DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

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