POLY-MED, INC.

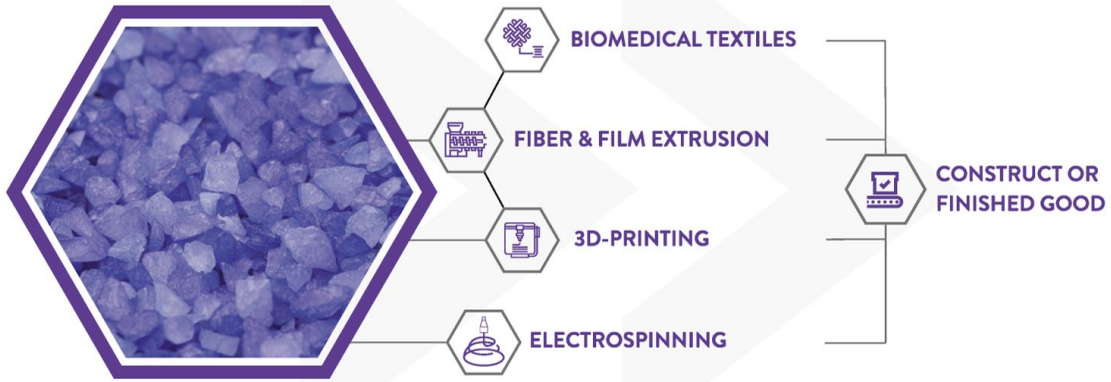
Medical Grade Polymers for Non-Implantable Applications: Standard Development

June 10, 2026

What makes a polymer ‘Medical Grade’

Trying to answer this with a new ASTM standard

Poly-Med's mission is to design, develop, and manufacture custom biotechnology materials to propel specialty product visions into tangible, highly competitive, & unique product offerings.



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ASTM Writing Task Group

The call for standardization…

- Common language
- Clear communication
- Manage expectations
- Understand risk
- For purposes of…
  - *Evaluating and specifying materials*
  - *Evaluating and managing change*

User Archetypes

Producer – Polymer Synthesis

- Chemical synthesis
- Can include additives

Producer – Compounder

- Melt or other addition
- Not a ‘part’

Distributor

- Possible Repackaging

Processor

- Process into a ‘part,’ including finished goods
- Not 510(k) or PMA owner

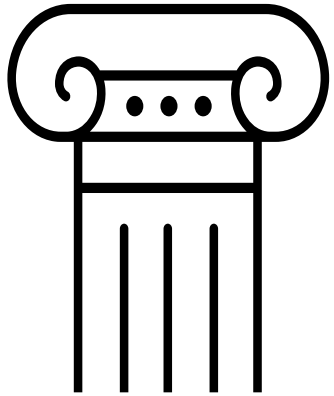
OEM

- Responsible for product risk
- 510(k) or PMA owner

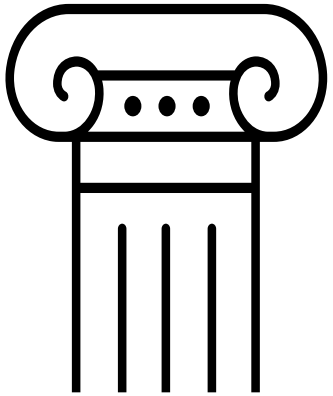
Polymer – responsible for chemistry

Part to Finished Device

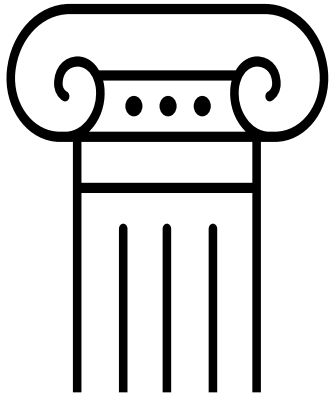
Quality Management



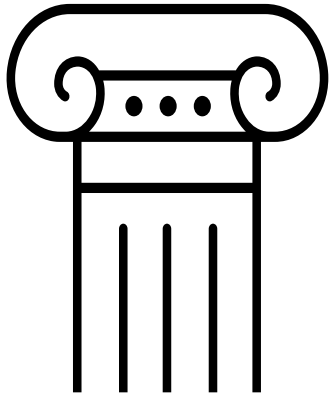
Regulatory Support



Traceability



Communication



References:

1. Medical Grade Plastics. VDI Verein Deutscher Ingenieure e.V. Published 2025.
2. Guidelines for the Classification of Medical-Grade Polymers Used in Nonimplantable Applications. Medical Grade Materials Consortium. Published 2025.

Goals for this Standard

- Transition a *Marketing Term* into a *Meaningful Term*
- Create *Common Language*
- Framework to *Manage Expectations* between Supplier and Purchaser

Rational (*As provided to ASTM F04 Committee*): There is no standard definition, or even industry norms, for the application of 'medical grade' or related terminology. This proposed guide will support purchasers (e.g. medical device component manufacturers, OEMs, etc.) and suppliers by creating a guide to support uniform application of terminology and expectations between these groups. Suppliers will be able to establish a clear value proposition, and purchasers will be able to communicate requirements and compare available suppliers more effectively. This guide may include recommendations to help establish the supplier / purchaser relationship. Application of this standard guide is intended to improve the safety, quality, and consistency of medical devices, with the patient being the ultimate benefactor.

Title and Scope

Guide for the Criteria and Classification of Medical Grade Polymers for Non-Implantable Applications

Scope

- This Guide will provide information for purchasers (e.g. Medical Device OEMs) and suppliers (e.g. medical polymer manufacturers) to **align expectations** of the essential requirements for **polymers** used in the manufacture of **non-implantable** medical devices, in vitro diagnostics, and packaging and to create a harmonized understanding of the application of 'medical grade' terminology.

- This Guide will address polymeric materials for a wide range of applications within the medical device and technology ecosystem but **excludes implantable applications** due to additional safety and regulatory requirements therefrom. This includes stratifying materials by classification for risk associated with the final application.

Title and Scope

Scope (*continued*)

- This Guide will address the need for polymeric materials that are **safe for their ultimate intended application** and **consistent in their manufacture and supply**.

- This Guide will be **limited to virgin grade resins**, which may include **polymeric materials that have been compounded with additives**, and does not include additional considerations for the use of recycled material(s) in part or whole. Any modification to materials performed by the user, including use of recycled content, and associated risks therefrom is the responsibility of the user.

Summary

A raw material evaluation cannot possibly determine whether a device is safe and effective and is not sufficient to eliminate all levels of risk, but high-quality raw materials and suppliers give a better chance to create high quality devices.

We want to provide a guide for evaluating a polymer to be used for *non-implantable* medical devices.

There is no requirement that a raw material must be ‘medical grade’ to be used in the manufacture of a medical device – we don’t want to change that, but…

Suppliers and purchasers will benefit from a standard framework to identify materials intended and controlled for medical devices.

THANK YOU

Questions? Comments?

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North America Medical-Grade Materials Consortium NAMGMC