Poly-Med, Inc.

Standardizing ‘Medical Grade’

ASTM Work Item Update

August 25, 2026

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What makes a polymer 'Medical Grade'

- Prior use in a medical device?
- Biocompatibility data?
- Extra manufacturing controls?
- More expensive?
- Because we say so?

There is no clear, consistent, or appropriate definition.
But this is something that we can attempt through MGMC, and ultimately with an ASTM standard.

M. Scott Taylor, PhD

Director, Product Engineering

Adjunct Faculty, Clemson University

ASTM Member, F04 and F42
→ Chair F04.11/.15 Joint Task Group for Absorbable Polymers

5,000+
Polymer Formulations

250+
Issued Patents

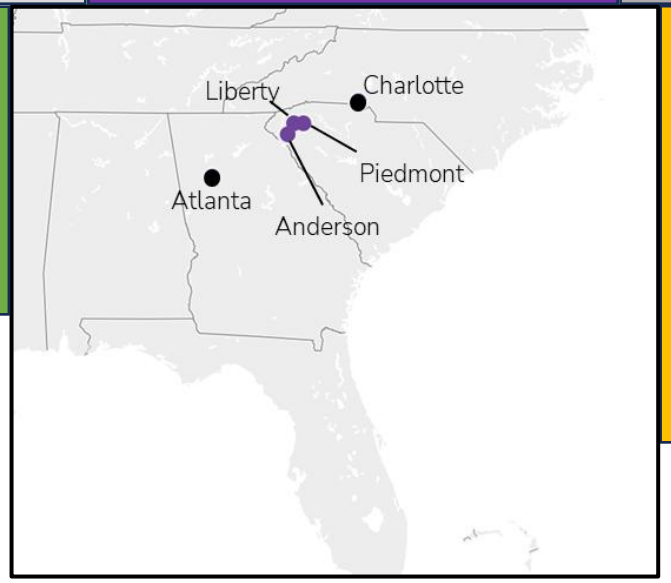
FDA Registered

ISO 13485

11,000,000+
Implantations

25%
Advanced Degrees on staff

33 Years
In Business



250+
Employees

ASTM Mission Statement

Helping our world work better by creating a foundation for trust, trade, and transformation through the power of global standardization

MGMC Goals

Develop a comprehensive definition of ‘medical-grade’ materials (excluding nonmedical and implant-grade) to establish a uniform set of criteria for defining these materials as an important step in helping manufacturers and regulators ensure that the materials used in manufacturing medical products meet their agreed-upon specifications. When fully harmonized, such criteria will simplify the selection and use of appropriate materials across the globe.

User Archetypes

Increasing responsibility and accountability →

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

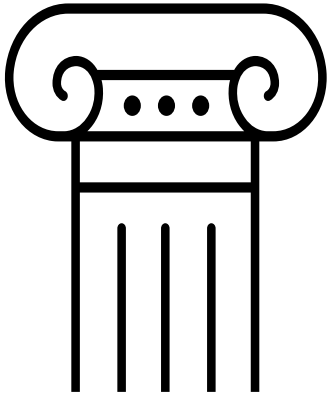
Part to Finished Device

The call for standardization…

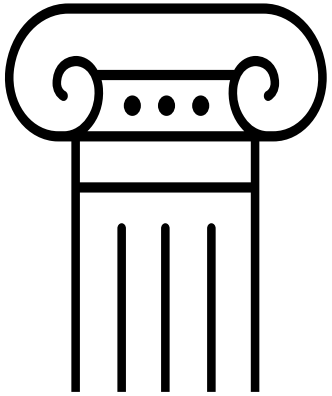
- Common language
- Clear communication
- Manage expectations
- Understand risk
- For purposes of…
  - *Evaluating and specifying materials*
  - *Evaluating and managing change*



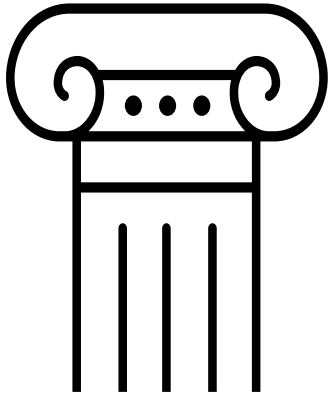
Quality Management



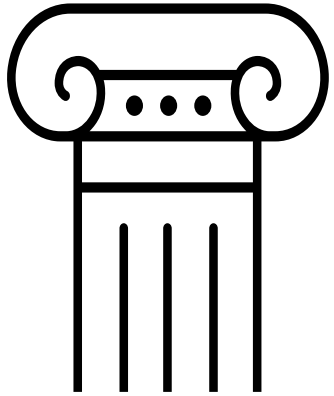
Regulatory Support



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 of this Standard

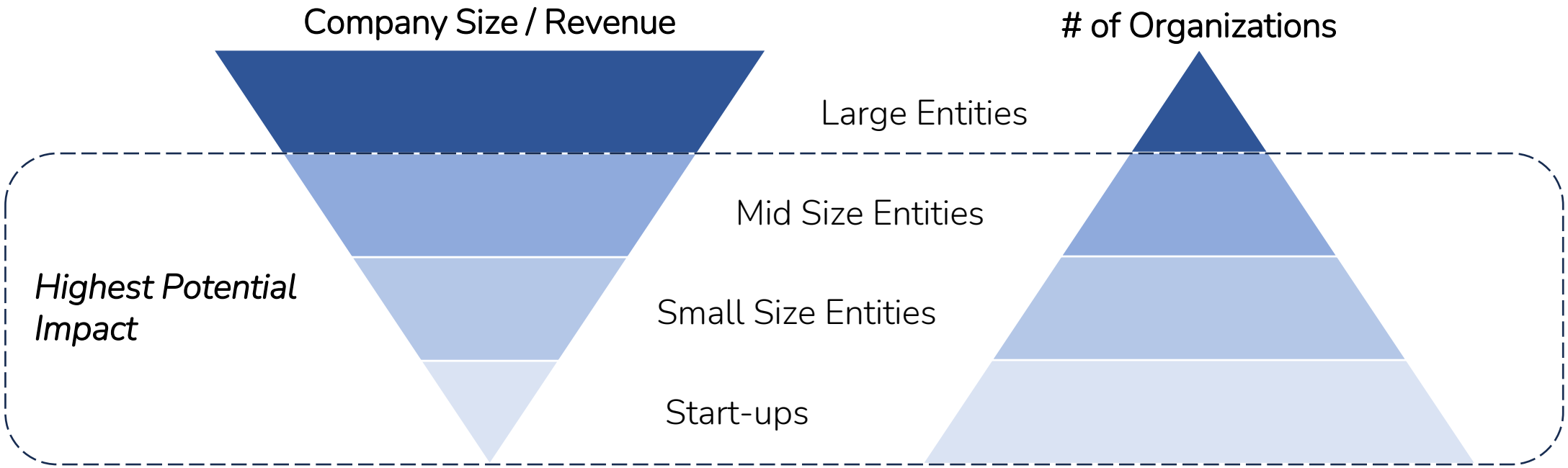
- Transition a ***Marketing Term*** into a ***Meaningful Term***
- Create ***Common Language***
- Framework to ***Manage Expectations*** between Supplier and Purchaser

Who is this for?

- *Purchasers, Suppliers*
- *Regulators*

What is this for?

- *Evaluating and specifying materials*
- *Evaluating and managing change*



ASTM Writing Task Group



Four Main Ideas

- Quality Management System and Change Control
- Know what is in the product, for example Lot Traceability
- Supportive Data, such as SDS and available biocompatibility
- Appropriate and Controlled Packaging

Title and Scope

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

Scope

- This Guide provides information for specification owners (e.g. medical device Original Equipment Manufacturers, or OEMs), purchasers (e.g. contract manufacturing organizations) 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 to create a harmonized understanding of the application of 'medical grade' terminology.

- This Guide addresses polymers (potentially referred to as plastic, resin, compound, composite, blends, and others) as raw or starting material for a wide range of non-implantable medical applications within the medical device industry but **excludes any implantable applications** due to additional safety and regulatory requirements therefrom.

Title and Scope

Scope (*continued*)

- This Guide addresses the need for polymers that are **safe for their ultimate intended application** and **consistent in their manufacture and supply**.

- This Guide is **limited to virgin grade polymers** that have been compounded with additives, and does not include guidance for the use of regrind, re-used polymer, or mechanically recycled material(s) in part or whole. Any modification to materials performed by anyone other than the supplier, including use of mechanically recycled content, and associated risks are the responsibility of the user.

- **Biocompatibility is addressed as one risk-stratified aspect of safety**, including references to existing standards, for example the ISO 10993 standard series, ASTM F748, and USP <1031>.

Title and Scope

Scope (*continued*)

- The following aspects are addressed to support the purchaser / supplier relationship:
  - Material characteristics,
  - Biocompatibility test status
  - Regulatory status (e.g. US FDA Master File, RoHS compliance)
  - Supply and quality recommendations

- Medical devices prepared using polymers in compliance with this guide may not necessarily result in a medical device suitable for its intended purpose. Additional testing specific to the medical device in its finished form, including, as applicable, manufacturing processes, cleaning, sterilization, packaging, environmental exposure, and storage, among other tests specific to the intended use are required.

Tools and Comps

Medtech Material Application Questionnaire / Design Form

NORTH AMERICA MGMC MEDICAL MATERIALS

Requested By: Date Requested: Date Needed:

Company Information*
Supplier Name:
Supplier Company:
Address:
Phone:
Email:

Customer Information*
Customer Name:
Customer Company:
Division:
Address:
Phone:
Email:

Material Information
Project Name:
Material Trade Name:
Color:
Compound:

Helpful information for a *PURCHASER* to provide to a *SUPPLIER*

Application Classification*
Packaging:
Packaging Type:
Type of Administration:
Oral Type:
Usage Method:
IVD:
FDA Medical Device Classification:
FDA Medical Device Classification, (please complete): 21 CFR:
Contact Duration:
Nature of Body Contact:
EU MDR Class:
Certification:

Process Information*
Process to Be Used:
If Other:
Region for Production:
In which countries will the final product be used:
Is the part a medical device according to: a. FDA (USA) NA ☐ Yes ☐ No ☐ b. European Medical Device Directive (MDD) NA ☐ Yes ☐ No ☐
Life cycle of device made from requested material?
Regulatory Requirements:
Asia Regulatory: List Below:

Application Information*
Application
Product End Use
Contact Type
Drug Form
Duration of Patient Contact
Laser Marking
Laser Marking Depth
Laser Welding
Radiopacity NA ☐ Yes ☐ No ☐
Antistatic NA ☐ Yes ☐ No ☐
Barrier Oxygen/Water NA ☐ Yes ☐ No ☐
UV Vis Blocking NA ☐ Yes ☐ No ☐
Nucleation NA ☐ Yes ☐ No ☐
Other
Sterilization NA ☐ Yes ☐ No ☐
Sterilization Method Used
If Other:
[1] If you chose Sterilization type Gamma or E-Beam, please indicate the total dose:
[2] If you chose Sterilization type Steam, please indicate the temp/time:
Critical Requirements
Additional Information / Comments:

Public Information Review

- Is there supportive information, e.g. Technical Data Sheets?
- Is there a QMS system, certification?
- Are there basic composition details (e.g., LDPE or glass-filled PEEK)?
- Is there a listed CAS number?
- Is there an identified polymer form (granule, powder, etc.)?
- Is there information about potential manufacturing process compatibility?
- Is there an SDS available?
- Is information about storage provided?
- Is there any information about chemical resistance or compatibility?
- Is there any information about sterilization compatibility?
- Is there biocompatibility data or a Master File that could be referenced?
- Are there other certifications or assessments that may be helpful?

Bormed™ HD850MO

Bormed HD850MO is a polypropylene homopolymer intended for evaluation for use in Healthcare applications.

Specifications | Downloads

Product specifications

BRAND NAME	Bormed™
PRODUCT TYPE	Polypropylene
PRODUCT SUB-TYPE	PP Homopolymers
INDUSTRY	Healthcare
APPLICATIONS	Medical Devices

General properties

MELT FLOW RATE	8 g/10min (230°C/2.16kg)

Specifications | Downloads

Documents

Select language: English

Data sheets

Product data sheet
Product Data Sheet · PDF · 1.6mb · Only available in English

Product safety information sheets
Safety Information Sheet · PDF · 145kb · English (European Union)

Product safety information sheets
Safety Information Sheet · PDF · 145kb · English (USA)

Product safety information sheets
Safety Information Sheet · PDF · 144kb · English (United Kingdom)

Declaration of compliance to food contact regulations
Compliance Statement · PDF · 201kb · English

Statement on chemicals, regulations and standards
Compliance Statement · PDF · 170kb · English

Statement on compliance to regulations on medical use
Compliance Statement · PDF · 133kb · English



Certificate AT21/3652.00

SGS

The management system of

BOREALIS AG

Trabrennstrasse 6-8, 1020 Wien, Austria

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The design, development, manufacturing, marketing & sales and distribution of polyolefin products and its compounds, olefin and base chemicals.

This certificate is valid from 24 June 2024 until 23 June 2027 and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 24 June 2021
Multiple certificates have been issued for this scope, the main certificate is numbered AT21/3652.00

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

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Page 1 / 3

General statements

Statement on PPWR as applied to Borealis products
Datasheets · PDF · 123kb · Only available in English

Statement on origin of additives
Datasheets · PDF · 96kb · Only available in English

Legal compliance of products confirmed in Borealis food contact statements issued before the publication of Regulation (EU) No 2023/1627
Datasheets · PDF · 73kb · Only available in English

Statement on Proposition 65 updates
Datasheets · PDF · 115kb · Only available in English

Borealis Polyolefin products based on chemically recycled feedstock (Borcycle™ C) in food contact applications in EU
Datasheets · PDF · 162kb · Only available in English

REACH Compliance Statement
Datasheets · PDF · 74kb · Only available in English

Statement on conflict minerals
Datasheets · PDF · 77kb · Only available in English

Borealis statement on SVHC in its polyolefin products
Datasheets · PDF · 124kb · Only available in English

General documents

Explanatory guidelines of the 'Borealis Statement on chemicals, regulations and standards'
Datasheets · PDF · 547kb · Only available in English

PRODUCT DATA SHEET

29.06.2022 Ed.5

Polypropylene

Bormed™ HD850MO

Polypropylene Homopolymer

Description

Bormed HD850MO is a polypropylene homopolymer intended for evaluation for use in Healthcare applications.

This medium melt flow grade gives exceptionally good dimensional stability to final products especially at higher temperatures (e.g. in autoclave). Its fa crystallisation and high crystallisation temperature enables shorter cycle time with reduced cooling time.

The Bormed concept is based on the three core principles of service, commitment and conformance which cover the different aspects of active information management, change control and security of supply. Because we care.

As part of the Bormed product portfolio, in case of notifiable change the grade can be made available up to 5 years (2 years pre-notification and last ca volume with 3 years shelf life); subject to mutual agreement.

Cas No. 9003-07-0

Typical characteristics

Bormed™ HD850MO can be described with following typical characteristics:

Very high stiffness	Sterilisation: EtO; steam
Good stiffness-impact balance	

Applications

Bormed™ HD850MO has been evaluated according to different regulations and standards. Typical applications are mentioned below for medical and diagnostic devices or pharmaceutical packaging. However, Borealis should be consulted for final approval to evaluate the use of Bormed™ HD850MO.

Diagnostic consumables and labware (e.g. pipette tips, tubes)	Filter housings for haemodialysis
Diagnostic devices (e.g. Point of Care)	Medical devices
Disposable 3-part syringes	Pharmaceutical caps and closures
Drug delivery systems (e.g. inhalers, auto injectors)	Plungers for syringes

The customer should be aware that Bormed™ products may only be used in applications which are pre-approved for evaluation by Borealis received ir the form of a risk assessment form (RAF) review response. Without such pre-approval, no use of the grade shall be made. In case of doubt, the customer should seek pre-approval for evaluation from Borealis to proceed through their sales or technical contact. Borealis makes no warranties beyond what is contained in this product datasheet and the customer is responsible for reading and accepting the disclaimer as contained in this product datasheet.

Physical properties

Property	Typical value *	Unit	Test method
Melt flow rate (230 °C/2.16 kg)	8	g/10min	ISO 1133-1
Flexural modulus	1850	MPa	ISO 178
Tensile modulus (1 mm/min)	1800	MPa	ISO 527-2
Tensile strain at yield (50 mm/min)	7.5	%	ISO 527-2
Tensile stress at yield (50 mm/min)	38	MPa	ISO 527-2
Charpy impact strength, notched (23 °C)	3	kJ/m²	ISO 179-1/1eA
Melting temperature	162	°C	ISO 11357-3
Heat deflection temperature B (0.45 MPa)	112	°C	ISO 75-2

* Data should not be used for specification work

Processing techniques

This product is easy to process with standard injection moulding machines. Following parameters should be used as guidelines:

Polypropylene

Bormed™ HD850MO

Processing setting	Typical value/range
Melt temperature	220 - 260 °C
Holding pressure [1]	200 - 500 bar
Mould temperature	15 - 60 °C
Injection speed	high

[1] *Minimum to avoid sink marks.*

Shrinkage 1 - 2 %, depending on wall thickness and moulding parameters.

Packaging and storage

Bormed HD850MO should be stored in dry conditions at temperatures below 50°C and protected from UV-light. Following aforementioned conditions the material can be stored for a period of up to 3 years after production. Improper storage can initiate degradation, which results in odour generation and colour changes and can have negative effects on the physical properties of this product.

Product compliance documents

Latest versions of product safety information sheets (PSIS), product safety data sheets (SDS) and other product liability documents are available in our website www.borealisgroup.com.

Sustainability aspects

Borealis is ever mindful of the impact of our products on the planet. We promote Design for Circularity (DfC) and Design for Recycling (DfR) to conserve natural resources and to reduce the environmental impact of products over their entire lifetime (including production, use phase and after phase). DfR helps ensure that material can be effectively recycled while maximizing the material performance efficiency. Further information on sustainability and Design for Recycling (DfR) can be found from our websites www.borealisgroup.com and www.borealiseverminds.com.

Disclaimer

The product(s) mentioned herein are not intended for use as medical implant material or implantable medical devices and we do not support their use for such applications.
To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however we do not assume any liability whatsoever for the accuracy and completeness of such information.
Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.
It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.
No liability can be accepted in respect of the use of any Borealis product in conjunction with any other products and/or materials. The information contained herein relates exclusively to our products when not used in conjunction with any other material unless as specifically provided for in the test methods stated above.

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Telephone: +43 1 22 400 0* | Fax: +43 1 22 400 333
www.borealisgroup.com

Borouge Pte Ltd | 1 George Street | # 18-01 | Singapore 049145
Telephone: +65 6275 4100 | Fax: +65 6377 1233
www.borouge.com

Bormed™ is a trademark of the Borealis Group

BOREALIS Borouge

STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

11.11.2025 Ed. 11

POLY-MED, INC.

Polypropylene
Bormed™ HD850MO

We confirm that this product fulfils the requirements on materials used for the manufacturing of articles or components of articles intended for medical use as described in:

Council of Europe	Material complies with the following European Pharmacopoeia monographs: Monograph 3.1.3. Polyolefins Monograph 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations Tests are made according to the current Pharmacopoeia edition at the time of the testing (11th edition). Monograph 3.2.2. Plastic containers and closures for pharmaceutical use: This monograph relates specifically to the container and closure system and does not contain tests that are required for compliance assessment of the raw materials used for said container and closures. The composition of the product is in compliance with this monograph.
Germany	The product follows the VDI 2017 Guideline on "Medical Grade Plastic" that covers the requirements for change management, quality management, supply security and support for regulatory requirements.
USA	Material has passed the following United States Pharmacopeia tests: Biological reactivity tests - in vitro <87>: Cytotoxicity (Elution test) Biological reactivity tests - in vivo <88>: Class VI - 70 °C Plastic materials of construction <661.1>: Identification, physicochemical and extractable metals (as listed in the chapter) tests. Plastic additive tests are done according to Borealis' internal methods. Tests are made according to the current Pharmacopeia edition at the time of the testing (USP 2021).
Additional testing	Material has been tested according to the following ISO 10993 biological tests, in the extent applicable for polymer pellets: Cytotoxicity (ISO 10993-5) Acute systemic toxicity (ISO 10993-11) Skin irritation / intracutaneous reactivity (ISO 10993-23) Dermal sensitization (ISO 10993-10) Hemocompatibility (ISO 10993-4) Tests are made according to the current ISO 10993 edition at the time of the testing (2021).
Elemental impurities	During the manufacturing process of this product, we neither use nor intentionally incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D(R2) Guideline on Elemental Impurities (May 2022).
DMF number	Material has been assigned the FDA Drug Master File number(s): DMF 017929
Additional information	If a customer wishes to take advantage of the pre-notice period in case of deletion or modification of Bormed grades, such pre-notice period needs to be included in Technical Delivery Specifications. This edition of the document supersedes any previous editions. Borealis reserves the right to modify this document at any time, so please ensure to view it frequently. Changes to this document may be made with or without notice. Please always ensure that you are viewing the latest edition by downloading documents directly from our website at www.borealisgroup.com.

VICTREX™ PEEK POLYMER 90P

High performance thermoplastic material, unreinforced PolyEtherEtherKetone (PEEK), semi crystalline, coarse powder for extrusion compounding, very easy flow, colour natural.

Last updated: 17 March 2026

REQUEST A QUOTE | DOWNLOAD PDF

Material Properties			
Physical	**Nominal Value**	**Unit**	**Test Method**
Density	1.30	g/cm³	ISO 1183
Mechanical	**Nominal Value**	**Unit**	**Test Method**
Tensile Modulus (23°C)	4100	MPa	ISO 527-1
Tensile Stress (Yield, 23°C)	100	MPa	ISO 527-2
Tensile Strain (Break, 23°C)	5.0	%	ISO 527-2
Flexural Modulus (23°C)	3900	MPa	ISO 178

VICTREX PEEK extrusion processing guide

VICTREX PEEK finishing operations guide

VICTREX PEEK properties guide (imperial units)

VICTREX PEEK injection moulding processing guide

Fluid & Gas Management with Confidence (interactive e-book)
Explore how Victrex's tailored PEEK and PAEK products meet critical fluid and gas management needs. This eBoo...

VICTREX PEEK Seal Ring Solutions
Reliable operation and improved efficiency in seal ring applications

BUREAU VERITAS

Bureau Veritas Certification

Victrex Manufacturing Limited

Bureau Veritas Certification Holding SAS - UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

The following site is part of the Management System of the above organisation:

Victrex Manufacturing Limited - Portsmouth

Victrex Manufacturing Limited, Trafalgar Wharf, Hamilton Road, Portsmouth, PO6 4PX, United Kingdom

Design, manufacture and sales of high performance polyketones and extruded pipe.

Certificate No.: UK014990-005 Version: 1 Issue date: 15-08-2025

The validity of this certificate depends on the validity of the main certificate, which expires on: ***14-11-2026***

UKAS MANAGEMENT SYSTEMS 0008

Signed on behalf of BVCH SAS UK Branch

Certification Body Address: 5th Floor, 100 Lower Thames Street, London, EC3R 6DL, United Kingdom

Local Office: 5th Floor, 100 Lower Thames Street, London, EC3R 6DL, United Kingdom

Further clarifications regarding the scope and validity of this certificate, and the applicability of the management system requirements, please call: +44 (0) 345 600 1828

CER CERTIF ALL TPL 002 Rev 4.3 4 Nov 2024

1/1

Document Reference:
MED-MSDS-010
PEEK-CLASSIX™
BC1;BC2;BC3

Invibio
BIOMATERIAL SOLUTIONS

Revision: 8
Date: 25-September-2025

SAFETY DATA SHEET

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH) & 1272/2008 (CLP)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	PEEK-CLASSIX™ BC1, BC2 and BC3 granules

1.2 Other means of identification

CAS No.	PEEK Polymer (31694-16-3 or 29658-26-2)
EC No.	Not applicable.
REACH Registration No.	Not applicable.

1.3 Recommended use of the substance and restrictions on use

Identified use(s)	The material is designed for medical device applications requiring blood or tissue contact for less than 30 days The materials are generally used for injection moulding, extrusion or machining operations.
Uses advised against	This material is not for long term implantation

Polymers (10)

Additive Manufacturing Filament Fusion Processing Guidelines

VICTREX PEEK properties guide (metric units)

VICTREX PEEK chemical resistance brochure

VICTREX PEEK compression molding processing guide

VICTREX PEEK extrusion processing guide

VICTREX PEEK finishing operations guide

VICTREX PEEK properties guide (imperial units)

VICTREX PEEK injection moulding processing guide

Fluid & Gas Management with Confidence (interactive e-book)
Explore how Victrex's tailored PEEK and PAEK products meet critical fluid and gas management needs. This eBoo...

VICTREX PEEK Seal Ring Solutions
Reliable operation and improved efficiency in seal ring applications

CHEMICAL RESISTANCE

VICTREX™ PEEK Polymers

victrex

Chemical	23°C	100°C	200°C
ACIDS			
Acetic Acid, 10% Conc.	A	A	
Acetic Acid, Conc.	A	A	A
Acetic Acid, Glacial	A	A	
Acrylic Acid	A	A	
Aqua Regia	C	C	C
Benzene Sulfonic Acid	C		
Benzoic Acid	A	A	
Boric Acid	A	A	
Carbolic Acid	A		
Carbonic Acid	A	A	
Chloroacetic Acid	A	A	
Chlorosulfonic Acid	C	C	C
Chromic Acid, 40% Conc.	A		
Chromic Acid, Conc.	C	C	C
Citric Acid	A	A	
Formic Acid	B	B	
Hydrobromic Acid	C	C	C

Chemical	23°C	100°C	200°C
ALCOHOLS			
Benzyl Alcohol	A		
Butanol	A		
Cyclohexanol	A		
Ethanol	A	A	
Ethylene Glycol	A	A	B
Ethylene Glycol, 50% Conc.	A	A	A
Glycerol	A		
Gylcols	A	A	
Isopropanol	A		
Methanol	A	A	
Propanol	A		
ALDEHYDES AND KETONES			
Acetaldehyde	A	A	
Acetone	A	A	
Benzaldehyde	A		
Cyclohexanone	A		
Formaldehyde	A	A	

KEY AND INTERPRETATION

Test bars of unfilled PEEK were immersed in chemicals at constant temperature for a minimum of 7 days (concentrated, unless otherwise stated). Chemical compatibility was assessed via retention of mechanical properties, supplemented by weight or dimensional changes when applicable. Compatibility was then classified into A, B, or C which should be interpreted as follows:

A – No interaction. Victrex materials are likely to operate in these chemicals. It is nevertheless recommended to validate the application performance.

B – Slight interaction. Victrex materials could be used in some applications exposed to these chemicals. It is necessary to evaluate the application specific performance criteria.

C – Severe interaction. Victrex materials should only be considered for applications with exposure to these chemicals under exceptional circumstances.

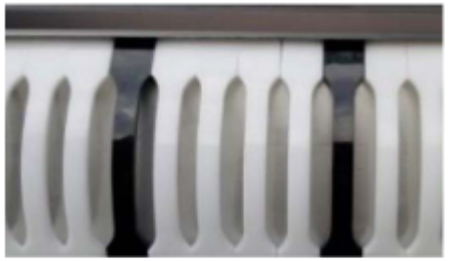
Sterilization and chemical resistance

Frequent cleaning and sterilization are critical to stem the spread of disease in healthcare settings. The materials that make up medical devices, whether single-use or multi-use, must continue to perform through these processes.

A semi-crystalline polymer, Delrin withstands many chemicals commonly used in the healthcare industry for analysis, cleaning and disinfection (Figure 7), or as drug carriers or conserving agents. Delrin also withstands common sterilization processes, such as ethylene oxide (EtO) and a number of repeat autoclave cycles.

Figure 7. Chemical resistance testing of Delrin

Tensile strength after 96-hour exposure (>80% retention)



2.5% Bleach solution
3% Peroxide solution
Ethanol Quaternary ammonium solution Clorox®* Healthcare Bleach Spray Lysol®* Mold and Mildew Sani-HyPerCide®* Germicide Sani-Cloth®* AF3 Wipes Virex® Tb*

* Trademark of its respective company

Factors such as temperature, chemical concentration, exposure time, part surface-to-weight ratio and stress level can all affect performance. For this reason, it is highly recommended to conduct a realistic end-use test to determine suitability for a particular application.

Premium Control grades

- Manufactured according to GMP principles
- Food contact statements (EU/FDA)
- Tested against selected parts of USP Class VI
- Tested against relevant parts of ISO 10993
- Sterilization data
- Global availability
- FDA drug master files available (DMF)
- Extended change notification

CERTIFICATE

dqs

This is to certify that

Delrin Netherlands B.V.

Baanhoekweg 22
3313 LA Dordrecht
Netherlands

has implemented and maintains a **Quality Management System**.

Scope:
Manufacturing of acetal resins.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	31625542 QM15
Date of original certification	2025-08-18
Date of certification	2025-08-18
Valid until	2028-08-17

ANAB ACCREDITED

IAF

DQS Inc.

David Tellez
Managing Director

Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA
The validity of the certification can only be verified by the QR-code.

Program Summary

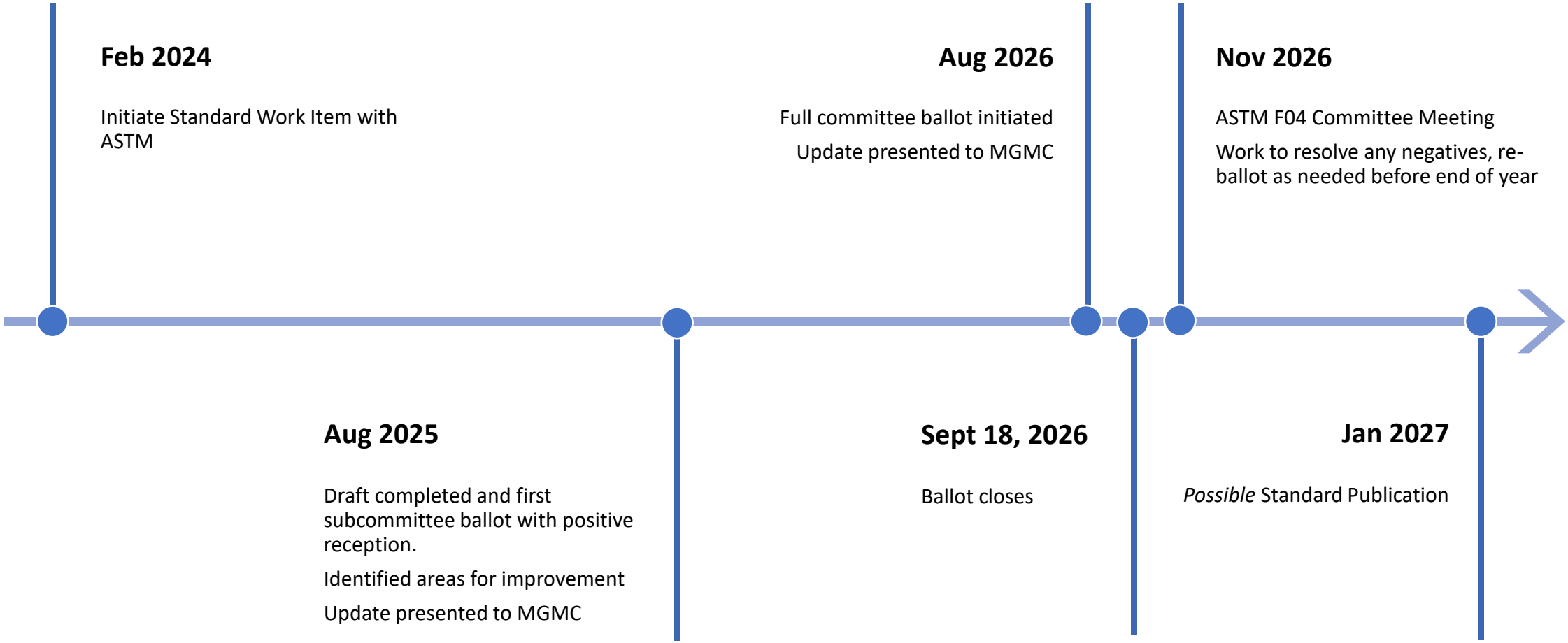
A raw material evaluation cannot possibly determine whether a device is safe and effective and is not sufficient to eliminate all levels of risk, but high-quality raw materials and suppliers give a better chance to create high quality devices.

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

There is no requirements 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 can benefit from a standard framework to identify materials intended and controlled for medical devices.

Progress Summary



THANK YOU!

QUESTIONS?

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North America Medical-Grade Materials Consortium, NA-MGMC