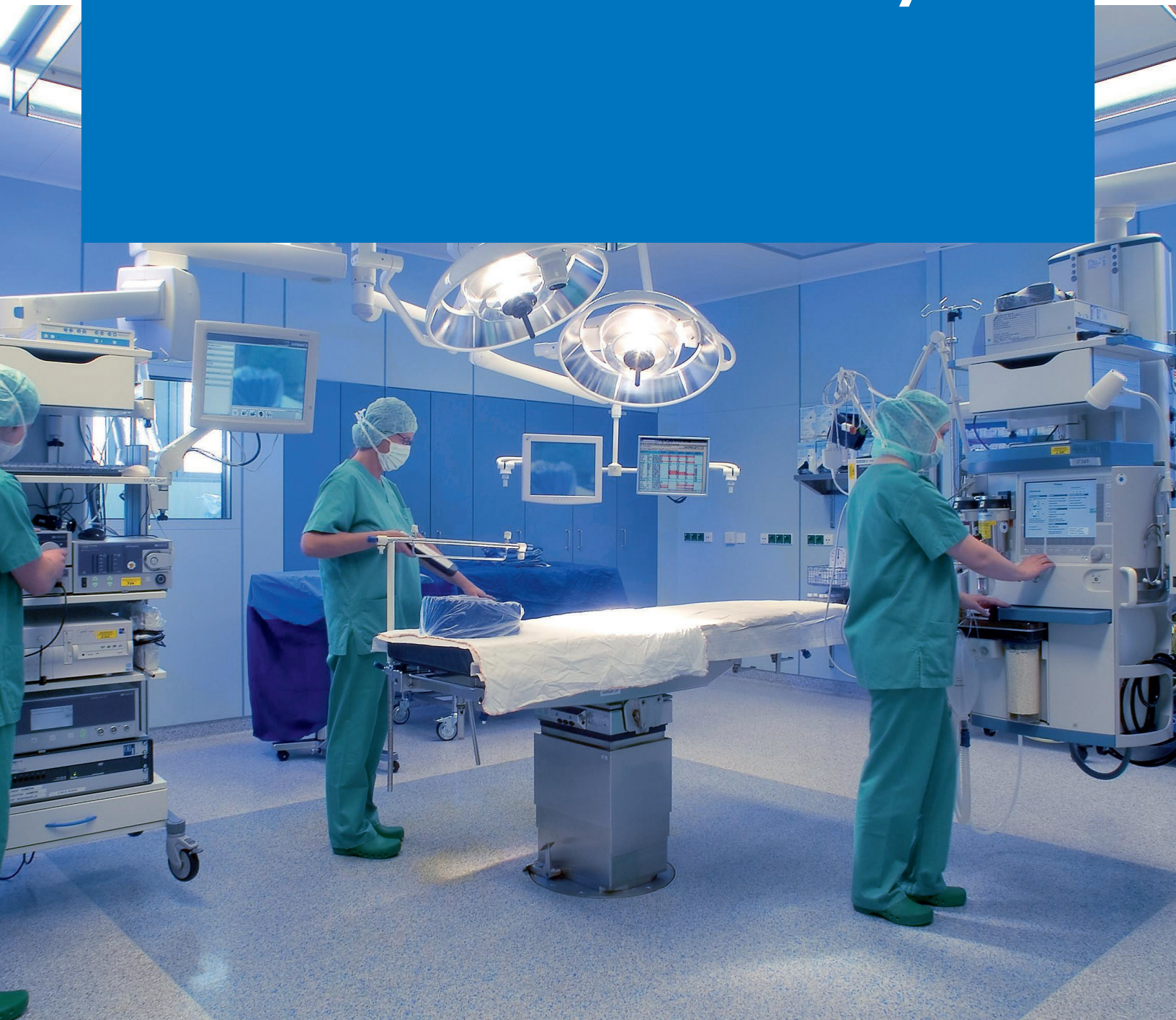


Engineering and High-Performance Plastics for the Healthcare Industry



Röchling • Competence in plastics

ISO 13485 Certified Shaping the Future through Innovation!

Röchling stands for innovation in plastics – we continuously strive to offer new and inventive products that meet the highest standards and changing requirements of the Life Science industry.

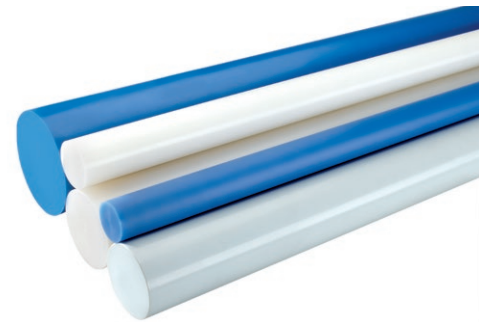
We are certified to ISO 13485: 2016, the Medical Device Standard that represents the requirements for a comprehensive management system for the design and manufacturing of medical devices. As a stock shape manufacturer of rods and sheets, our quality procedures include key elements such as resin and process validation, product inspection, lot and batch traceability (Device History Record), risk management analysis, corrective and preventive actions and customer feedback.

Our customers can be assured that our medical-grade products meet their expectations and comply with regulatory requirements. We offer full lot and batch traceability, detailed certification documents and raw material Certificate of Analysis.

We manufacture a complete line of engineering and high-performance plastics in rods and sheets for applications including surgical instruments and devices, orthopedic sizing trials, imaging and monitoring components, surgical trays and caddies, diagnostic and analytical equipment, pharmaceutical manufacturing and biotechnology equipment.

Röchling Industrial North America shares your commitment to innovation and quality. Increasingly, the physical properties of high-performance plastics such as impact resistance, dimensional stability and resistance to autoclaving pave the way for new medical device and component designs. For questions relating to material selection and specifications, rely on our expert knowledge.

As a member of Röchling, we are a leading global plastics manufacturer with a workforce of nearly 11,000 employees with 90 locations in 25 countries. Today, Röchling ranks among the top international leaders in the field of plastics processing.





Requirements for medical technology

With **medical-grade (MG)** materials, our product range that has been specifically developed with orthopedic, healthcare technology in mind is at your disposal.

Biocompatibility

With the raw materials deployed, we utilize plastics and additives that have already been in use in medical-technical applications for many years now. The raw materials are FDA-compliant, free from heavy metals, and comply with the EU directives.

Chemical resistance

Medical-grade materials possess good chemical resistance to various conventional disinfectants and cleansers.

Sterilization performance

A great number of our high-performance materials are very easily sterilizable by means of hot steam, ethylene oxide, plasma and gamma rays.

Traceability

Röchling offers complete lot and batch traceability for medical-grade materials, from semi-finished products right up to the raw materials.

FDA compatibility

The majority of our high-performance materials meet FDA requirements.

Many colors of our MG products have also been tested in regards to these guidelines.

Hydrolysis resistance

The excellent hydrolysis resistance of our MG products is indispensable for the ability to sterilize with hot steam.

Physiological harmlessness

ISO 10993

Biological evaluation of Medical Devices per ISO 10993

ISO 10993 includes a series of tests for evaluating the biocompatibility of a medical device prior to a clinical trial. Compliance to ISO 10993-5 (tests for in vitro cytotoxicity) is typically the most requested for applications requiring high-performance plastics.

Many of our products have been tested and approved by an independent lab to ISO 10993. Our products are often produced with raw materials that are certified for approval.

USP Class VI

Biological tests per USP Class VI

USP tests are used to determine the biological reactivity of plastic materials. Most of our products are USP VI (systemic and intracutaneous toxicity) compliant.

Food contact guidelines

Compliance with FDA Regulation CFR21

Based on the data from the raw material supplier, we can provide a certification for direct contact with food for a large number of our materials. It is derived from the FDA regulation "Code of Federal Regulations" 21 CFR, Part 177.

Biocompatibility

Within the scope of selecting the suitable material for a medical-technical application, not only the technical requirements have to be considered, but often it is necessary to ensure the material is compatible with the human organism. The biological assessment of a product is invariably requisite, if there is direct contact of the material or product with the patient.

The extent of such tests depends particularly on the experience already gained for this material in the particular application concerned, and the precise intended use of the medical product (in particular the nature and duration of the physical contact).

The chief basic regulations for biological testing and assessment of materials are ISO 10993 and testing as per United States Pharmacopeia Class VI (USP Class VI for short). Despite the fact that the clearly more comprehensive ISO 10993 was originally meant to supersede testing as per USP Class VI, USP testing is very frequently referred to today to assess plastics.

There are various test results for biocompatibility according to ISO 10993 and USP Class VI available for the medical-grade materials from Röchling.

Ultrasonic Testing

We perform ultrasonic testing on all medical-grade products to ensure that there are no cracks, voids, or impurities.



Product overview

Material selection

High performance plastics are generally defined by their ability to maintain their physical properties under thermal, chemical or electrical stress, while operating at elevated temperatures above 300° F. These materials typically feature high strength and stiffness as well as outstanding chemical resistance and electrical properties.

Engineering plastics are among the most common and useful thermoplastics and typically exhibit good mechanical properties. These materials generally have one or two main attributes that best fit the needs of the application and should be taken into consideration when deciding on a specific plastic.

Amorphous thermoplastics are mostly transparent or translucent due to their polymer structure. Their mechanical properties remain almost unchanged over a wide temperature range, frequently right up to their continuous operating temperature. They are susceptible to stress cracking and this should be taken into account when machining them. Amorphous plastics include PEI, PSU, PC and PPO.

Partially crystalline thermoplastics are a result of the molecular arrangement, usually being opaque. The mechanical properties (strength, toughness and hardness) of this group depend to a great extent on the degree of crystallinity. They feature great resistance to the formation of stress cracks and very good chemical resistance. Partially crystalline plastics include acetal, PP and PEEK.



**Sustason®
PPSU MG
(Radel® R5500)**

Sustason® PPSU MG offers incredible toughness in applications that receive repeated sterilization. With a high heat deflection temperature of 420° F it can absorb tremendous impact without cracking or breaking.

PRODUCT FEATURES:

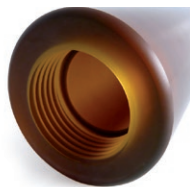
- Excellent thermal stability
- High impact resistance
- Resistance to repeated autoclaving
- Resistance to hydrolysis

CERTIFICATIONS:

- ISO 10993-5 Certified
- USP Class VI ASTM D6394
- FDA compliant

Products	Sizes	Colors
Sheets	3/8" – 2" x 24" x 48"	● ● ● ● ●
Rods	1/4" – 6" diameter	● ● ● ● ●

Colors available: Natural (bone), Black, Blue, Grey and Green.
Custom colors available



**SustaPEI
MG
(ULTEM™ HU1000)**

SustaPEI MG (ULTEM™) is an amorphous transparent polyetherimide plastic that offers outstanding high heat resistance (up to 356° F), high strength and a broad chemical resistance.

PRODUCT FEATURES:

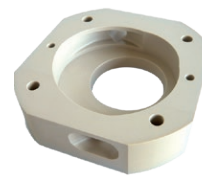
- Strength and modulus at elevated temperatures
- Inherent flame resistance
- Gamma radiation resistance
- Excellent resistance to steam sterilization

CERTIFICATIONS:

- ISO 10993 compliant, USP Class VI
- ASTM D5205
- Meets FDA 210 CFR 177.1595

Products	Sizes	Colors
Sheets	3/8" – 4" x 24" x 48"	● ● ● ● ●
Rods	3/8" – 6" diameter	● ● ● ● ●

Colors available: Natural (amber), Black, Blue, Grey and Green



**SustaPEEK
MG**

SustaPEEK MG is increasingly replacing metals and other lower grade plastics in the healthcare industry due to its superior physical properties, including chemical resistance and high temperature stability.

PRODUCT FEATURES:

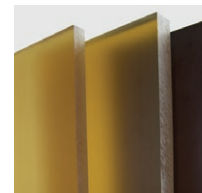
- Continuous use temperature of 480°F
- Outstanding dimensional stability
- High chemical resistance
- Excellent resistance to sterilization

CERTIFICATIONS:

- ISO 10993-5 compliant, USP Class VI
- ASTM D6262
- FDA compliant

Products	Sizes	Colors
Sheets	1/4" – 4" x 24" x 48"	● ● ● ● ●
Rods	1/4" – 6" diameter	● ● ● ● ●

Colors available: Natural (tan), Black, Blue, Brown, Yellow and Green



**Sustason®
PSU MG
(Polysulfone)**

Sustason® PSU MG is an amorphous semi-transparent thermoplastic with an amber tint. Due to its inherent resistance to hot water and steam, it is regularly used in medical applications where repeated sterilization is required.

PRODUCT FEATURES:

- Continuous use temperature of 300°F
- Long-term resistance to steam sterilization
- Resistant to hydrolysis
- Strength and dimensional stability

CERTIFICATIONS:

- ISO 10993 compliant, USP Class VI
- ASTM D6394
- FDA compliant

Products	Sizes	Colors
Sheets	3/8" – 2" x 24" x 48"	● ●
Rods	3/8" – 6" diameter	● ●

Colors available: Natural (amber) and White



Sustarin® C MG (Hostaform® MT2U06)

Sustarin® C MG is easy to machine to close tolerances and is very dimensionally stable. The material has excellent wear properties and low coefficient of friction.

PRODUCT FEATURES:

- Excellent dimensional stability
- Easy to machine to close tolerances
- Porosity free
- Available in multiple colors

CERTIFICATIONS:

- ISO 10993-5 compliant, USP Class VI
- ASTM D6100
- FDA21 CFR 177.2470 compliant

Products	Sizes	Colors
Sheets	3/8" – 4" x 24" x 48"	● ● ● ● ● ● ● ●
Rods	3/8" – 8" diameter	● ● ● ● ● ● ● ●

Colors available: Natural, Blue, Red, Orange, Yellow, Green, Brown and Grey
Custom colors available



Sustanat® PC MG (Polycarbonate)

Sustanat® PC is ideally suited for applications that demand high impact strength. It is an amorphous, transparent product that exhibits good electrical and mechanical properties along with excellent dimensional stability.

PRODUCT FEATURES:

- Continuous use temperature of 250° F
- Easy to machine to close tolerances
- High impact strength
- Good electrical insulation

CERTIFICATIONS:

- ASTM D6098 PC 0111
- ASTM D3935 PC 0111
- Natural meets FDA 21 CFR 177.1582
- USP Class VI compliant

Products	Sizes	Colors
Sheets	1/4" – 4" x 24" x 48"	●
Rods	3/8" – 8" diameter	●

Color available: Natural



Polystone® P MG (Polypropylene)

The superior physical properties of Polystone® P MG is a compression molded polypropylene that is manufactured by a unique heat stabilization process. This product is easily machined and is specifically designed for surgical trays and caddies.

PRODUCT FEATURES:

- Excellent dimensional stability
- Resistant to steam autoclaving
- Laser markable
- Low moisture absorption

CERTIFICATIONS:

- ISO 10993-5 certified
- FDA compliant

Products	Sizes	Colors
Sheets	1/2" – 3" x 24" x 48"	● ●
Sheets	1/2" – 3" x 40" x 48"	● ●

Colors available: Black and White

General notes

All the information contained in this product range has been researched to the best of our knowledge. Nonetheless, errors cannot be completely precluded. For this reason, the information contained in the present product range does not involve any kind of obligation or warranty. Accordingly, we therefore do not undertake any responsibility nor any resultant or any other liability, arising in any manner from utilisation of this information. No responsibility is undertaken either for the completeness of the products, processes, properties, etc. covered. Data concerning weights are purely computed values, ensuing from the density and the mean value of the tolerance dimensions.

Our medical grade semi-finished products are not intended for the manufacture of implants, permanent oral implants, or dental contact of more than twenty-four (24) hours with body fluids and/or tissues/bones. The processors and marketers of medical devices are advised that any intended application must be carefully

examined. In the EU, medical products may only be placed on the market if they have been CE-marked in the procedure provided for them and also fulfill all the requirements of the respective relevant legislation. The sole responsibility for the evaluation of the end product for the intended use and compliance with the applicable requirements lies solely with the manufacturer/marketer of the respective product/end product.

Application of Roechling materials not intended for implants

The materials described in this product range are not suitable for application as medical implants. Furthermore, they should not be put to use in medical technical fields, necessitating direct, long-term contact of the material with the patient.

Sterilization and multiple use of medical products

For classification of the sterilization resistance of our materials, various criteria were referred to, such as change to the mechanical properties, change in weight or loss in transparency (amorphous materials). For these reasons, this assessment only represents recommendations and not definite commitment for the suitability of a material for a specific reprocessing procedure. Should the medical product be reused, it is incumbent upon the manufacturer of the product to determine the suitability and the number of possible reprocessing cycles for a process.

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Material properties and applications

Material			Specific Gravity	Tensile Strength	Tensile Modulus	Tensile Elongation Break	Flexural Strength	Flexural Modulus
Trade Name	Common Name		D792	D638 PSI	D638 PSI	D638 %	D790 PSI	D790 PSI
PPSU Sustason® PPSU MG	Radel® R5500		1.29	11,000	390,000	30	15,500	350,000
POM C Sustarin® C MG	Hostaform® MT2U06		1.41	9,500	400,000	40	12,000	400,000
PEEK SustaPEEK MG	PEEK		1.32	16,000	500,000	20	25,000	600,000
PEI SustaPEI MG	ULTEM™ HUI000		1.27	16,700	480,000	80	20,000	500,000
PSU Sustason® PSU MG	Polysulfone		1.24	10,200	360,000	30	15,400	390,000
PC Sustanat® PC MG	Polycarbonate		1.20	10,000	320,000	75	13,000	340,000
PP Polystone® P MG	Heat-stabilized Polypropylene		0.91	4,700	232,000	-	-	180,000

Material			Rockwell Hardness	Izod Impact Notched	Heat Deflection Temp. @ 66 psi	Heat Deflection Temp. @ 264 psi	Continuous Use	Volume Resistivity
Trade Name	Common Name		D785 R	D256 ft. lb/in	D648 °F	D648 °F	°F	D257 ohm-cm
PPSU Sustason® PPSU MG	Radel® R5500		R120	13.0	417	420	320	10 ¹⁶
POM C Sustarin® C MG	Hostaform® MT2U06		R120	1.2	320	225	180	10 ¹⁶
PEEK SustaPEEK MG	PEEK		R126	1.2	360	320	480	10 ¹⁵
PEI SustaPEI MG	ULTEM™ HUI000		R123	0.6	405	395	340	10 ¹⁶
PSU Sustason® PSU MG	Polysulfone		R125	1.3	359	345	300	10 ¹⁶
PC Sustanat® PC MG	Polycarbonate		R126	10.0	295	280	250	>10 ¹³
PP Polystone® P MG	Heat-stabilized Polypropylene		-	1.9	221	149	180	-

Statistics based on resin data, not stock shape. Individual testing for stock shapes can be provided upon request.

Applications for medical technology

Today, finished products machined from our plastics are used in a host of medical devices and instruments. For applications requiring proven biocompatibility we offer a variety of medical-grade materials as well as a comprehensive offering of standard plastics for applications that do not come into direct contact with patients.

Surgical instruments and supplies

- Handles and grips for instrumentation
- Sizing trials for knee and hip replacement
- Endoscopic housings and eyepieces
- Sterilization trays and caddies

Diagnostic

- Parts for X-ray and MRI devices
- Components for supports and biopsy units

Therapeutic systems

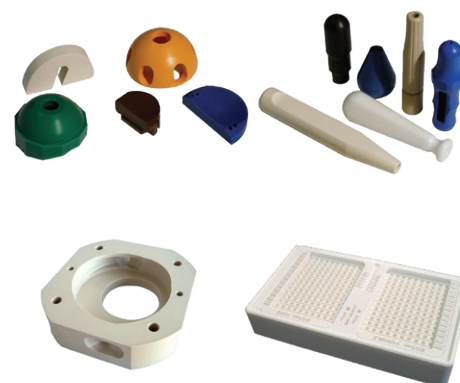
- Blocks and housings for dialysis machines
- Pistons and valves for anesthetic equipment
- Supports and adaptors for respiratory units

Dental

- Grips and handles for dental instruments
- Components for treatment and therapy units

Pharmaceutical and biotechnology

- Components for sample changers
- Valve housings and nozzles for fluid distribution
- Spectrometer parts for chromatography systems
- Wear parts for pill and tablet production



Biocompatibility and sterilization performance

Biocompatibility

Biocompatible implies that a medical device is safe for human use. The ISO 10993 standard plays an important role in the assessment of the biocompatibility of a medical device through a series of tests depending on the intended use and the time that it is exposed to the human body. Most importantly, the ISO 10993-5 test method assesses the in vitro cytotoxicity of medical devices and is designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

Sterilization and disinfection

An essential aspect of selecting a suitable plastic for a medical technology application is also the requirement for repeated sterilization and disinfection of the product. The cleaning process typically occurs in autoclaving devices at elevated temperatures (greater than 250° F) with steam or suitable disinfectants. The resistance of the polymer should be checked in each case.

Selection of the tests as per ISO 10993-5

			Biological risks											
Nature of the physical contact		Duration of contact	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic toxicity	Carcinogenicity	Reproductive/ Developmental Toxicity	Degradation
Medical products with contact to body surfaces	Skin	A	x	x	x									
		B	x	x	x									
	Mucous membrane	C	x	x	x	•	x	x	•		•			
		A	x	x	x									
	Injured surface	B	x	x	x	•	•		•					
		C	x	x	x	x	x	x	•		•	•		
Medical products, coming into contact with the interior of the body from outside	Blood system indirectly	A	x	x	x	x					x			
		B	x	x	x	x	•				x			
	Tissue / bone / dentin	C	x	x	x	x	x	x	x		x	•		
		A	x	x	x	•								
	Circulating blood	B	x	x	x	x	x	x	x	x				
		C	x	x	x	x	x	x	x	x	•	•		
Implantable medical products	Tissue / bone	A	x	x	x	•								
		B	x	x	x	x	x	x	x					
	Blood	C	x	x	x	x	x	x	x	x	•	•		
		A	x	x	x	x		•	x	x				

x Test to be included to ISO 10993-5

• Additional tests, which may be applicable

A = short-term (= 24 h) B = protracted (> 24 h to 30 d)

C = continuous (> 30 d)

Sterilization resistance ¹⁾		Sterilization procedure/ °F ²⁾					
Material	Polymer	Hot steam		Hot air	Ethylene oxide	Plasma	Gamma rays
		250°F	273°F	356°F	140°F	113°F	RT ³⁾
Polystone® P MG	PP-H	↑↑	↑↑	↓	↔	↑	↔
Sustarin® C MG	POM-C	↑	↔	↓	↑	↑	↓
SustaPEEK MG	PEEK	↑↑	↑↑	↑↑	↑↑	↑↑	↑↑
Sustason® PSU MG	PSU	↑↑	↑	↓	↑	↑	↑
Sustason® PPSU MG	PPSU	↑↑	↑↑	↑↑	↑↑	↑↑	↑↑
SustaPEI MG	PEI	↑↑	↑↑	↑↑	↑↑	↑↑	↑↑
Sustanat® PC MG	PC	↔	↓	↓	↑	↑	↔

¹⁾ with the changes to the mechanical properties being taken into due account

²⁾ Guide values

³⁾ RT = room temperature



very good resistance



good resistance



conditional resistance (number of cycles limited)



no resistance



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