

Your high-performance supplier for the Healthcare industry

- Competences in semi-finished products, machined components, additive manufacturing & assembly groups
- Thermoplastics & Composites
- Clean room production



Healthcare

European Market



Röchling Group

The Röchling Group has been shaping industry. Worldwide. For more than 200 years. We transform the lives of people every day with our customized plastics: they reduce the weight of cars, make medication packaging more secure and improve industrial applications. Our workforce of 11,400 people is located in the places where our customers are – in 84 sites in 25 countries. The Group's three divisions generated joint annual sales of 2,592 million euros in 2025.

Content

Röchling Group	2
Röchling Industrial	3
Quality is our standard	4
Innovation management	5
Chapter 1 Materials – an unparalleled range	6
Chapter 1 Medical & Healthcare grades – product overview	7
Chapter 1 Healthcare & Medical grades – additional information	8
Chapter 2 Additive manufacturing processes	9
Chapter 2 Machining competence	10
Chapter 3 Application examples: Surgery	12
Chapter 3 Application examples: Life Science	14
Chapter 3 Application examples: Pharma	16
Chapter 3 Application examples: Diagnostics	18
Chapter 4 Delivery program	20
Chapter 5 General notes	22
Chapter 5 Regulatory affairs/quality assurance	23

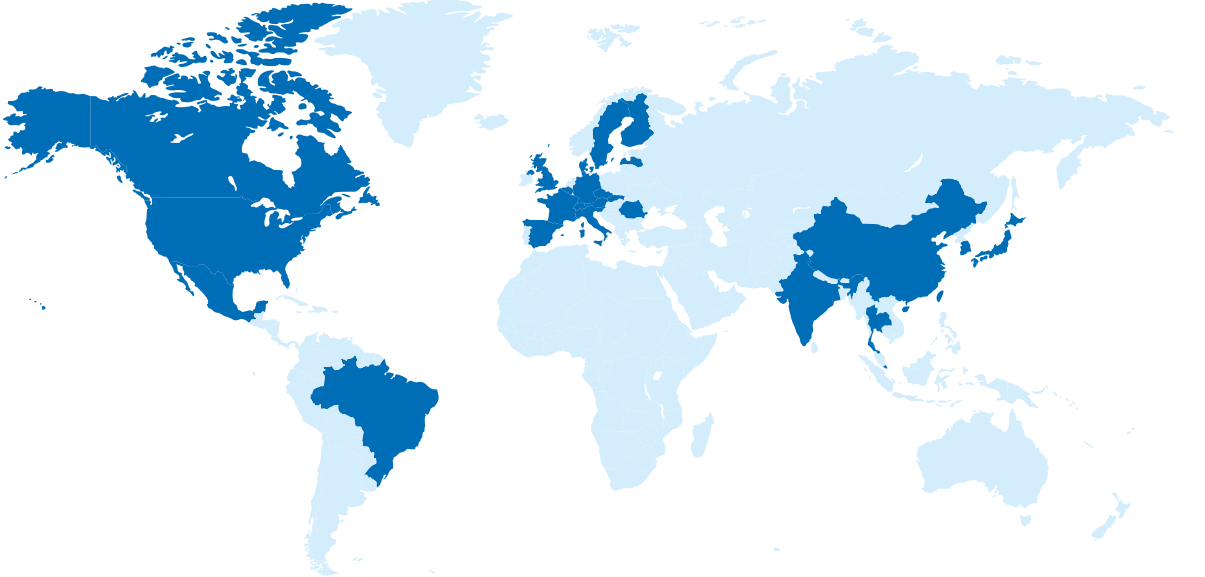
Röchling Industrial

Empowering Healthcare

At Röchling Industrial we develop and supply individual products made of plastic for all industrial areas. We have one of the broadest product ranges of thermoplastics as well as composite materials and supply our customers with the highest quality standards and the latest technologies – from the semi-finished product over machined components, additive manufacturing to assembly groups, we at Röchling Industrial can fulfill all your needs. The product portfolio is completed by high-quality, customised and end-to-end OEM products from our Röchling Medical Division using mainly injection moulding and blow moulding technologies.

Our one-of-a-kind, international network of companies within Röchling Industrial provides customers in the Healthcare industry with material of highest quality, outstanding industry know-how, newest machinery set-up and precision machining services wherever you are located. Our competence of Röchling Industrial for the Healthcare industry is specifically divided in the fields of surgery, life science, pharma and diagnostics. We at Röchling work closely together to further improve medical care including product safety and patient benefits with new, innovative products and materials.

In this brochure we present you the product range for the Healthcare industry from Röchling Industrial.



America	Europe				Asia
Brazil Itupeva Jundiaí	Austria Oepping	Germany Mannheim (HQ) Bad Grönenbach-Thal Brensbach Burgrieden Cologne Geeste-Dalum Haren Lahnstein Lützen Munich Nentershausen Neuhaus am Rennweg Peine Roding Ruppertsweiler Troisdorf Vreden Waldachtal Weidenberg Worms Xanten	Great Britain Gloucester High Peak Hitchin	Spain Araia Bocairent Teruel	China Changchun Chongqing Chuzhou Hefei Kunshan Shenyang Suzhou
Canada Orangeville, ON	Belgium Gijzegem		Italy Abbiategrosso Gozzano Laives Trento Venegono Inferiore Volpiano	Sweden Virserum	
Mexico Silao	Czech Republic Koprivnice Nové Mesto na Morave Tábor			Switzerland Weinfelden	India Bangalore Mumbai Pune Vadodara
USA Akron, OH Cleveland, OH Dallas, NC Denver, PA Duncan, SC Kimberly, WI Mount Pleasant, PA Ontario, CA Rochester, NY Southfield, MI	Denmark Allingåbro		Latvia Liepaja		Japan Tokyo Yokohama
	Finland Rusko		Romania Pitești		Singapore Singapore
	France Décines Maxéville Paris		Slovakia Nové Mesto nad Váhom		South Korea Asan Hwaseong-si
					Thailand Chon Buri

The illustration covers all Röchling locations worldwide.



Quality is our standard

We at Röchling Industrial use our “Integrated Management System” to work continuously on the systematic optimisation of all quality factors. The quality of our products is our success as we are customer/patient driven. Our certified quality management systems according to DIN EN ISO 9001:2015 for our healthcare grades and additionally the ISO 13485:2016 for our medical grades ensure that our products meet your requirements. The manufactured products are permanently subjected to different quality tests in all phases of production. Besides, we can deliver you directly from our ISO Class 7 Clean room.



Let's improve medical care

As the world's population rises and becomes ever older, the need for modern and efficient medical care takes on increasing importance. Few sectors place such high requirements on products, devices and equipment. Safe, innovative and reliable materials are essential to meet the high standards of modern medical care.

To develop and manufacture products for the safe treatment of patients and to further improve medical care we offer you a unique range of thermoplastic and composite materials available as semi-finished products and machined components.

Semi-finished products

Europe's largest stock of biocompatible plastic and therefore a wide product range of thermoplastic as well as composite materials available as:

- Sheets
- Rods
- Tubes
- Cut-to-size service

Machined components

Machining capabilities to manufacture components that will function optimally in your application:

- Assisting with the configuration and design of your components
- Support from the selection of suitable materials to the final product
- From prototyping to series production

Innovation management

Innovation is an essential driver of growth in the Healthcare industry. At the same time new products for the healthcare sector have to fulfill high demands in terms of functionality and safety. That is why a key part of our service for the Healthcare industry is our innovation management. Together we develop completely new products and parts specifically for your application, to further improve medical care. We as ONE Röchling Group are your high-performance supplier for healthcare plastics from the first steps to the final product – and beyond.

- We accompany you in this process from the generation of ideas, the development of business models, to the implementation and economical production of the new product until the market launch!
- We know that, especially in the Healthcare industry, regulatory aspects often pose high demands. Because of this we offer you 360-degree support for the entire development process – from product design and manufacture to the regulations and the approval procedures.
- To accomplish this, we have, if appropriate, the help of a large network of universities and companies including the start-up scene.



Sustainability

As a family company, we at Röchling stand for value-based and sustainable action. We apply the very same principles in our approach to the environment and society that we apply to our customers, partners and employees: mutual respect, great regard and considerable trust.

Our corporate culture systematically promotes sustainable developments: At Röchling Industrial we consistently invest in sustainable products and infrastructure. As part of the plastics industry, it is clear to us that sustainability must be understood and implemented holistically. This is how we create added value on an economic, ecological and social level.

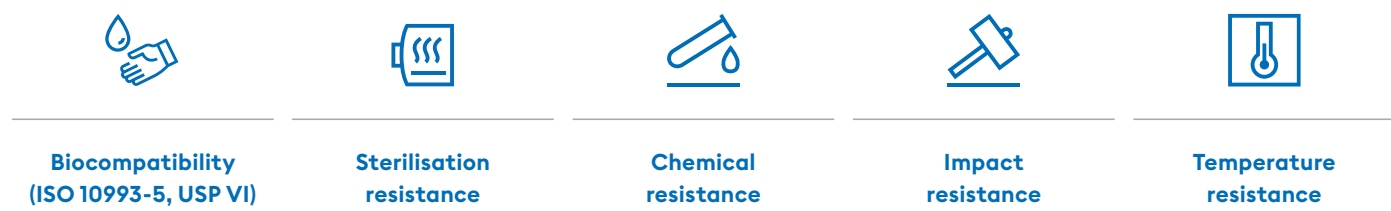
Chapter 1 | Materials – an unparalleled range

For more than 100 years we have specialised in the processing of plastics. Today, our product range is comprised of more than 350 different types of thermoplastic and composite materials, with a variety of modifications and special developments available.

The performance and service life of materials used in the healthcare sector are influenced by a variety of factors. These factors must be taken into account in order to select the right materials. Examples:

- Contact with detergents and disinfectants
- Requirements on surface quality
- Design conditions
- Dimensions and tolerances

We are happy to support you in fulfilling your requirements. For more specifications and details get in touch with us!



With in the pyramid shown wide range of materials, we support the different requirements of each industry sector. Besides our Composites (e.g. Durostone® and Glastic®) our qualified and proven material include for example:

Thermoplastics

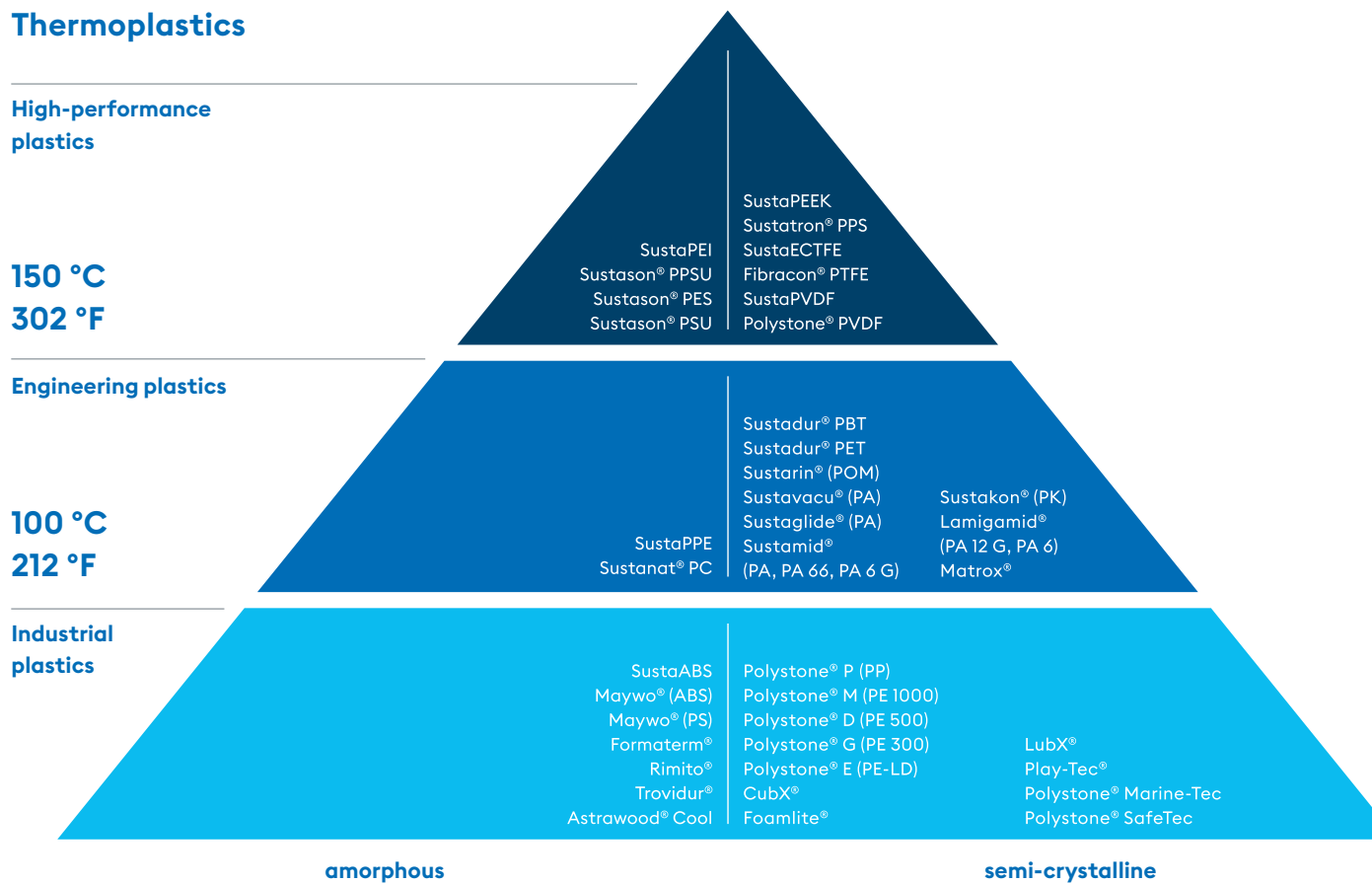
High-performance plastics

150 °C
302 °F

Engineering plastics

100 °C
212 °F

Industrial plastics



Chapter 1 | Medical & Healthcare grades – product overview

Please see Röchling Industrial's portfolio of semi-finished products for medical & healthcare applications with exposure of less than 24 hours, considering the biocompatibility requirements, sterilization resistance and regulatory aspects such as the Food and Drug Administration FDA compliance as well as the Regulation (EU) 2017/745, also known as the Medical Device Regulation (MDR). In general, our Röchling Industrial portfolio is not suitable neither for medical devices in risk class III, for those with permanent oral or dental contact, nor for the manufacturing of medical implants.

			Biocompatibility		Compliance			Sterilisation resistance			
	Polymer	Location	ISO 10993-5	USP Class VI	MDR ⁽²⁾	FDA ⁽²⁾	ISO 13485	Hot Steam [134°C]	Ethylene oxide [60°C]	Plasma [45°C]	Gamma rays ⁽³⁾ [RT]
Medical Grades ⁽¹⁾											
The Medical Grade (MG) portfolio is focused on medical devices for the risk classes I, IIa and IIb with less than 24 hours exposure. The use in implantable devices are not allowed. Therefore, those products are intended to be used for medical devices in accordance with the Regulation (EU) 2017/745, especially when it comes into direct short-term contact to the human body fluids and/or tissue respectively bones.											
SustaPEEK MG	PEEK	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	> 2,000 ⁽⁵⁾	●	●	●
		USA	✓	✓	✓	✓	✓	> 2,000 ⁽⁵⁾	●	●	●
Sustason® PPSU MG	PPSU	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	> 2,000 ⁽⁶⁾	●	●	●
		USA	✓	✓	✓	✓	✓	> 2,000 ⁽⁶⁾	●	●	●
SustaPEI MG	PEI	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	> 2,000 ⁽⁷⁾	●	●	●
		USA	✓	✓	✓	✓	✓	> 2,000 ⁽⁷⁾	●	●	●
Sustason® PSU MG	PSU	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	> 500 ⁽⁸⁾	●	●	●
ProMeX® MG EHS	PP	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	> 500 ⁽⁹⁾	◐	◐	◐
ProMeX® MG	PP	GER	✓ ⁽⁴⁾	✓ ⁽⁴⁾	✓	✓	✓	–	○	◐	○
Healthcare Grades ⁽¹⁾											
The Healthcare Grades (HG) are not intended to be used for medical devices in accordance with the Regulation (EU) 2017/745. Therefore, those products are not suitable for the manufacture of medical implants, critical components of medical devices with direct contact to the human body, fluids and/or tissue respectively bones, permanent oral or dental contact.											
SustaPVDF HG	PVDF	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	> 1,000 ⁽¹¹⁾	●	●	●
Polystone® PVDF HG	PVDF	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	> 1,000 ⁽¹¹⁾	●	●	●
Polystone® P HG EHS	PP	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	> 500 ⁽¹²⁾	◐	◐	◐
Polystone® P HG HI	PP-B	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	> 500 ⁽¹²⁾	◐	◐	◐
Polystone® P HG	PP	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	–	○	◐	○
Polystone® G HG	PE-HD	GER	✓ ⁽¹⁰⁾	✓ ⁽¹⁰⁾	–	✓	–	–	○	◐	●

Abbreviations: MDR = Medical Device Regulation, FDA = Food and Drug Administration, MG = Medical Grade, HG = Healthcare Grade, EHS = Extra Heat Stabilised, HI = High Impact, RT = Room Temperature

✓ yes ✓ optional upon request

● very good resistance ● good resistance ○ conditional resistance – no resistance/not applicable

- (1) The distributor, processor and user of the respective product, manufactured from our semi-finished products, are exclusively responsible for evaluating the end product's compliance with applicable legal requirements and its intended use.
- (2) Not all colours approved according to MDR Regulation (EU) 2017/745 and/or FDA 21 CFR 178.3297 Colorants for polymers. For more details ask one of our experts or visit the website (<https://www.roechling.com/industrial/materials>).
- (3) NB: Sterilisation by gamma irradiation can alter the technical properties and color of plastic.
- (4) Biocompatibility tests were conducted on defined regular basis directly on semi-finished products manufactured by Röchling, however not each batch number. This is optional and upon request available. Additional information relies on the material respectively resin supplier.
- (5) According to DIN EN ISO 17665-1:2006-II "Test report for long term reprocessing stability study" performed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AAI793, Version: V4, Date: 26.06.2023.
- (6) According to DIN EN ISO 17665-1:2006-II "Test report for long term reprocessing stability study" performed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AAI794, Version: V4, Date: 26.06.2023.
- (7) According to DIN EN ISO 17665-1:2006-II "Test report for long term reprocessing stability study" performed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AAI795, Version: V4, Date: 26.06.2023.
- (8) Based solely on information published by the resin supplier. For more information get in touch with us.
- (9) Röchling Industrial, Quality Investigation Report (QIR), Titel: Sterilisationsprozess von thermoplastischen Kunststoffen, Document No.: QIR_TH_2022-05, Rev.: 000, Date: 2022-09-08
- (10) Biocompatibility can be conducted upon request according to your specification. This can be either done by the resin supplier or directly on semi-finished products manufactured by Röchling. For more information get in touch with us.
- (11) Röchling Industrial, Quality Investigation Report (QIR), Titel: Prüfbericht zur Langzeitstudie zur Aufbereitungsstabilität, Document No.: QIR_TH_PVDF_2026-06-04, Rev.: 000, Date: 2026-06-04
- (12) According to DIN EN ISO 17665-1:2006-II "Test report for long term reprocessing stability study" performed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AAI790, Version: V3, Date: 26.06.2023.



Chapter 1 | Healthcare & Medical grades – additional information

Medical Grade (MG)

In certain cases, materials must meet specific regulations if they are to be used in medical devices. Our Medical Grade (MG) products provide specially developed materials for medical engineering. With the documentation of all relevant processes as well as product information combined with consistently quality controls, we are able to fulfill the necessary requirements. The highest quality is our standard. Our MG portfolio is focused on ISO 10993 Type A “medical” applications with less than 24 hours exposure.

Healthcare Grade (HG)

Besides our MG product portfolio, we can offer you an additional product range explicit for the Healthcare industry – including pharma, diagnostic and life science applications. A wide range of different production possibilities and specific colours complete our service package explicit for you. The HG portfolio is not intended to be used for medical devices in accordance with the Regulation (EU) 2017/745 such as medical implants, critical components of medical devices with direct contact to the human body, fluids and/or tissue respectively bones, permanent oral or dental contact.

Biocompatibility

For several of our medical & healthcare products there are test results for biocompatibility according to ISO 10993-5 and the USP <88> Class VI available on request. The tests were conducted either from the raw material supplier or on the semi-finished product manufactured by using our internal standard procedures.

DIN EN ISO 10993-5

The scope of biocompatibility testing according to ISO 10993-5 depends on the nature and duration of physical contact. When selecting a suitable material for a medical-technical application, it is necessary to consider not only the technical requirements, but also the biocompatibility. It is also necessary to ensure that the material is compatible with the human body. Therefore, the test depends essentially on the intended application.

USP Class VI

USP tests are used to determine the biological reactivity of plastic materials. The test meets the requirements of the guidelines for the biological test for plastics, Class VI under the controlled conditions: 70 °C for 24 hours. We have listed all our USP VI (systemic and intracutaneous toxicity) compliant products on the “Product Overview”. If you need further test requirements, we are happy to advise you from the first steps within your process.

Sterilisation resistance

Riskless re-use presupposes a safe method to kill off all microorganisms on the surface of this equipment. Accordingly, an essential aspect for selecting the suitable plastic for a medical technology application, is also the requirement for cleaning, repeated disinfection, and sterilisation of the product. The most important processes for plastics are steam sterilisation, radiation as well as ethylene oxide sterilisation.

Traceability

Röchling offers a full traceability for all medical & healthcare products, allowing them to be traced from the semi-finished product right back to the batch of raw materials. Our ISO 13485:2016 and DIN EN ISO 9001:2015 compliant quality management system enables us to ensure that the relevant requirements are met, verified, and documented.

Medical Device Regulation (MDR)

All resins are high-quality materials from reputable sources conforming with the Regulation (EU) 2017/745 in explicit Annex I, Chapter 10.4.1. (MDR). This section outlines three specific device classes: devices that (1) “are invasive and come into direct contact with the human body” (2) “(re)administer medicines, body liquids or other substances, including gases, to/from the body” (3) “transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body.”

U.S. Food and Drug Administration (FDA)

The compliance of their chemical composition with the food safety and hygiene requirements laid down by the FDA – in explicit FDA 21 CFR 178.3297 “Colorants for polymers” – is confirmed by the manufacturers. Besides it is our standard to have the correct master file (MAF) number available for our MG and HG portfolio.

In general

The distributor, processor and user of the respective product, manufactured from our semi-finished products, are exclusively responsible for evaluating the end product’s compliance with applicable legal requirements and its intended use.

Chapter 2 | Additive manufacturing processes

As a key technology, additive manufacturing processes complement our wide range of technologies. Additive manufacturing is the industrial production process that creates three dimensional components by depositing material layer by layer. With its variety of possible materials and the almost unlimited freedom of design, additive manufacturing is predestined to realise innovative parts for the Healthcare industry. 3D-printing offers entirely new ways to design and manufacture your components. Conventional products and processes for the Healthcare industry can be completely redesigned and product morphologies can be realised that cannot be manufactured using traditional processes. At our modern and scalable factory, we utilise multiple technologies in the field of additive manufacturing and can offer support for:

- Rapid prototyping
- Small batches
- Engineered products and customisation
- In situ manufacturing

Materials available

Engineering plastics

- Functional prototypes
- Complex geometries
- High-strength parts
- Different surface finishing options

Let us
rethink your
product!

Technologies



Multi Jet Fusion (MJF): Printing with polymer powder and binding agent.



Fused Deposition Modeling (FDM): Printing with plastic filament.



Selective Laser Sintering (SLS): Printing with polymer powder.

Properties

	PA12	PA2200	ABS
Modulos of elasticity	1,800 MPa (ASTM D638)	1,700 MPa (ISO 527)	2,400 MPa (ASTM D638)
Tensile strenght	48 MPa (ASTM D638)	50 MPa (ISO 527)	48 MPa (ASTM D638)
Elongation at break (XY)	20% (ASTM D638)	20% (ISO 527)	4% (ASTM D638)
Melting temperature	187 °C/369 °F	176 °C/349 °F	–
HDT (@ 0.45 MPa)	175 °C/350 °F (ASTM D648)	–	–
Vicat	–	163 °C/325 °F (ISO 306)	99 °C/210 °F (ASTM D1525)
Certification	ISO 10993-5/10993-10 and USP Class I–VI	USP Class VI	ISO 10993 and USP Class VI

Chapter 2 | Machining competence

How your part is realised

Components are required fulfilling the highest demands in terms of functionality, design and safety. As a leading plastic processor, we know the possibilities of different materials. With our comprehensive range of machining and production possibilities we realise components that will function optimally for your application.

- We assist you with the configuration and design of your components
- We provide you with support from material selection to design optimisation and precise machining
- High-precision CNC systems equipped with dry and wet processing as well as internally cooled tools
- Production of complex geometries and narrow tolerances (in the hundredths of a millimeter range), while at the same time maintaining a high degree of surface quality
- Using innovative turning and milling machines combined with highest automation technologies we provide you with a wide product range – starting from a size of 0.5 mm



Note: HG = Healthcare Grade | MG = Medical Grade
For further explanation see pages 7 and 8.

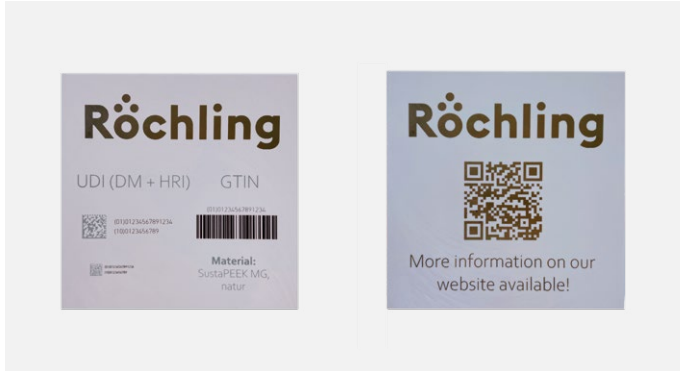
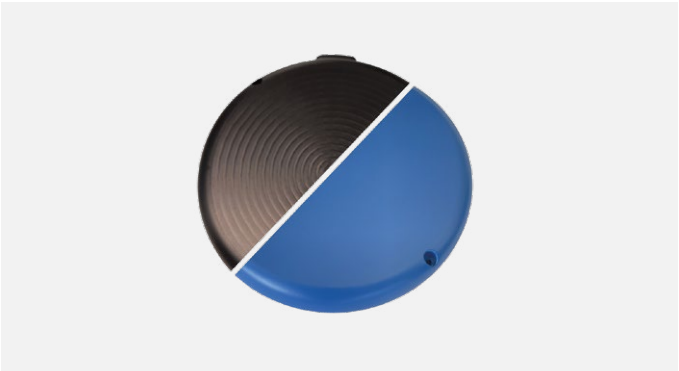
Our machining capabilities are rounded off with a broad range of additional services – from surface finishing to final packaging. You can decide which service you want for your product, and this will be delivered from ONE supplier. We are happy to work closely together in order to get these processes qualified within your quality system.



Surface finishing: Using modern technologies, we provide components with outstanding surface quality. Our options for surface finishing include blasting (mineral materials, metallic or organic nature), grinding, smoothing, polishing and varnishing.



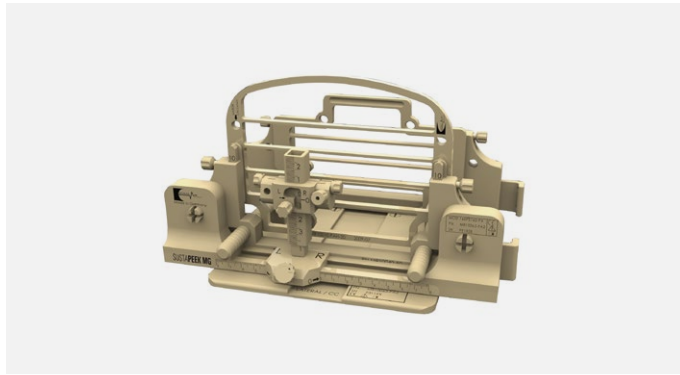
Marking: Individual parts can be marked UDI compliant (Datamatrix + HRI) as well as with any logos, emblems, serial-/article number, GTIN or construction codes. For this process laser marking and printing are available.



ISO Class 7 Clean room: Cleaning, drying, bagging and labelling of your critical parts by our trained staff in our certified ISO Class 7 Clean room to an established procedure.



Assembly groups: If you are looking for a simplified supply chain, with fewer orders to process and expedite, then make use of our kitting and assembly services. We can supply parts in kits or assembled and packaged to your specification.





Demands our materials fulfill:

- Sterilisation resistance
- Low specific weight
- Very high surface quality

Chapter 3 | Application examples: Surgery

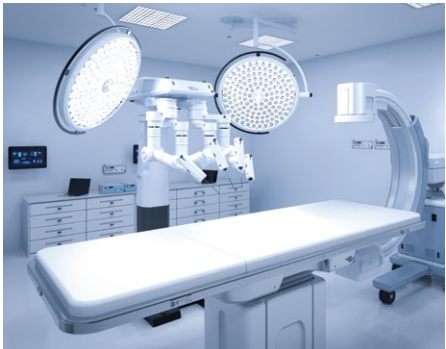
For surgeries on or in a patient's body various instruments and devices are required. We offer a wide range of materials and parts for this demanding medical field. We machine surgical instruments such as handles, surgical cutlery or camera housings as well as trial implants in many clearly visible colours. Beside this our high-performance materials are also used in minimally invasive surgery. For example, as an eyepiece funnel, guides or sliding elements.

When the intended use is a medical application in accordance with the Regulation (EU) 2017/745 our Medical Grade (MG) portfolio is your choice. It is especially engineered for ISO 10993 Type A "medical" applications with less than 24 hours exposure. For further explanation see pages 7 and 8.

Typical parts include:

- Handles
- Cutlery
- Housings
- Trial implants
- Funnels
- Guides
- Sliding elements

Product examples



Hygienic wall protection panels

- With easy to clean surface
- Supports high hygiene standards
- Suitable for walls, ceilings, doors and surfaces in operating theatres as well as in isolation wards and decontamination areas

Typical material requested:

- Trovidur EC-Clad AG+



Trial implants

- For example, for knee implants, hip socket implants and sockets
- Very high accuracy
- Very high surface quality
- Machined to tight tolerances according to customer drawings

Typical material requested:

- Sustason® PPSU MG

Case Study

Plastic components for endoscopes



Challenge:

Handles were previously made of metal. Customer approached us with these requirements:

- Lower weight than the previous metal construction
- Sterilisable
- Markings

Materials requested:

- SustaPEEK MG
- Sustason® PPSU MG

Our solution:

- Sustason® PPSU MG is lighter than metal, so surgeons can operate longer and more delicately
- Better feel, as plastic is warmer than metal
- Machined in tight tolerances
- Different colours make it easier to distinguish between instruments
- Sterilisation resistance over 1,000 cycles
- Surface finishing upon customer request

Case Study

Handle for surgical instruments



Challenge:

Customer approached us with these requirements:

- Sterilisable
- High quality feel and high surface quality
- Machined in tight tolerances

Materials requested:

- SustaPEEK MG
- Sustason® PPSU MG

Our solution:

SustaPEEK MG was chosen because of his special properties:

- Good stability required for manufacture (complex components & tight tolerances)
- Dissipative to heat
- Good thermal properties
- Good chemical resistance



Your advantages

- Long-lasting and low maintenance: due to excellent chemical resistant
- Economic production processes
- Good sealing efficiency
- Potential low risk of damage to critical equipment

Chapter 3 | Application examples: Life Science

Life science covers several branches of science, such as biology and medicine that deal with living organisms, often in relationship to drug development or analytics of living culture. Our materials can be utilised in machines to assist with reproductive science, pathology laboratories and even assisting with the understanding of genetic illness.

The Healthcare Grades (HG) could be a suitable solution for your requirements as long as there is only indirect contact to the human body fluids and/or tissue respectively bones. For further explanation see pages 7 and 8.

Typical parts include:

- Manifolds
- Housings
- Alignment segments
- Seals
- Nozzles
- Snap rings

Product examples



Centrifuge applications

- High strength and heat resistance
- Low weight
- High impact

Typical material requested:

- Polystone® P HG HI (black)



Manifold for cell cultivation and thermal expansion proper

- Components require excellent chemical resistance due to multiple experiments
- Good stability

Typical material requested:

- Polystone® P HG

Case Study

Alignment segment for mass spectrometry



Material requested:

- SustaPEEK

Our solution:

- Excellent dimensional stability achieved through precision machining
- Good thermal resistance to high temperatures
- Good chemical resistance (components are cleaned in ISO Class 7 Clean room before use)
- Cryogenically finished to achieve burr free components to avoid failure in critical electronics

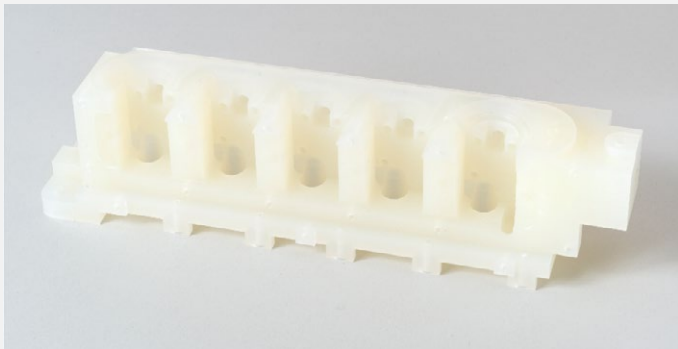
Challenge:

Customer approached us with these requirements:

- Critical surface finish of Ra 0.8
- Inspection under magnification of x24
- Complex 5-axis machining geometries

Case Study

Reservoir clamp main body



Material requested:

- Polystone® P HG

Our solution:

Polystone® P HG (natural) was chosen due to the following properties:

- High chemical resistance
- Low leachable and extractable behaviour during process
- Natural colour
- Sliding and wear properties with adjacent moving parts
- High temperature stability
- High dimensional stability with tight tolerances
- PPAP – 187 inspection points – CMM
- 5 Axis Milling with automated loading
- Dry ice deburring
- ISO Class 7 Clean room wash and pack

Challenge:

Customer approached us with these requirements:

- Dimensional stability
- Consistent quality in large batch quantities
- Sliding properties
- PPAP inspection



Manufacture of pharmaceutical products places specific demands on the materials. Requirements our materials fulfill include:

- Chemical resistance
- Material purity
- Zero extractables and leechables
- Easily cleaned/sterilised
- ESD & anti-static
- FDA and other approvals

Chapter 3 | Application examples: Pharma

The development of drugs is a lengthy and complex process. Manufacturer of pharmaceutical products place specific demands on machines, equipment and materials used. Our materials are used worldwide in applications in the pharma industry supporting the safe and economic development and production of drugs. The Healthcare Grades (HG) could be a suitable solution for your requirements as long as there is only indirect contact to the human body fluids and/or tissue respectively bones. For further explanation see pages 7 and 8.

Typical parts include:

- Seals
- Housings
- Guides
- Connectors
- Agitators
- Fixtures

Product examples



Pharmaceutical production

- High abrasion and wear resistance
- Low coefficient of friction
- Chemically resistant

Typical material requested:

- Sustadur® PET



Chromatography applications

- High strength and heat resistance
- Good processing properties
- Low weight

Typical material requested:

- Polystone® P HG

Case Study

Automatic line for filling and labelling drugs



Challenge:

- Customers required a sterile material that must be easy to clean and resistant to chemicals
- Material must be easy to machine into various shapes and sizes to suit a range of equipment

Material requested:

- Sustarin® C

Our solution:

- R&D phase involving material approvals and sample development
- Different variations of size
- Sterile and fully disposable
- No need for additional sterilisation or sanitisation procedures
- Assure drug quality and safeguard health
- Full scale-up range
- Double bagged packed in ISO Class 7 Clean room

Case Study

ESD and anti-static products for pharma production



Challenge:

- Customer required anti-static materials for products involved in manufacture of drugs from powder.

Materials requested:

- Polystone® G EL used for glove ports
- Polystone® M AST used for chutes and tubes
- Sustarin® C ESD 90 or Sustarin® C ESD 60 PLUS used for manifolds
- Fibracon® PTFE AS used for seals and flexible connections

Röchling materials offers the following advantages:

- ESD and AS materials dissipate static build up generated by the movement of the powders
- Easy to clean allowing a wide range of temperatures and cleaning agents
- Fully CNC machined



Specialist services

- Cleaning and deburring
- Part marking and labelling
- Kitting and assembly
- Clean room packing

Chapter 3 | Application examples: Diagnostics

If you are a medical device manufacturer or laboratory engaged in the diagnosis and treatment of illness, we have a range of products and services supporting your requirement for biologically inert materials and products. The most demanding level of accuracy and cleanliness are required with machined parts.

The Healthcare Grades (HG) could be a suitable solution for your requirements as long as there is only indirect contact to the human body fluids and/or tissue respectively bones. For further explanation see pages 7 and 8.

Typical parts include:

- Extraction spacers
- Load lock chambers
- Manifolds
- Housings
- Connectors
- Plate guides

Product examples



Durostone® components for MRT

- Durostone® glassfibre-reinforced material is permeable to magnetic fields making them excellently suited for use in magnetic resonance tomography (MRT)
- Components made of Durostone® include patient beds, coil supports made of coiled rings and spacers machined according to customer drawings

Typical material requested:

- Durostone®



Wear profiles for drug analysis

- Chemically resistant and good wear properties
- Good performance under high temperature

Typical material requested:

- Sustadur® PET

Case Study

Fluid chamber assembly



Challenge:

Customer approached us at design stage with the following challenges:

- Chamber assemblies with multiple item BOM's
- Complex supply chain – difficult to manage across multiple orders and suppliers
- 50% of chambers leaking on assembly

- Recurring problems with stress cracking on the PC items
- Cleanliness issues – regular returns to supplier due to foreign body contamination

Materials requested:

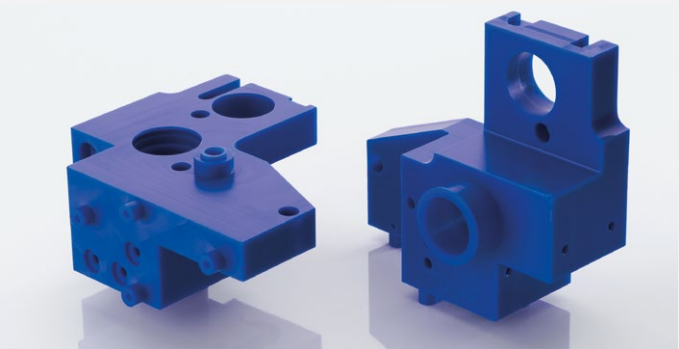
- Sustanat® PC
- Sustadur® PET
- Fibracon® PTFE

Our solution:

- Supply to customer fully assembled – for the customer all in one order
- Developed cutting and cleaning procedures to eliminate stress cracking
- Developed closed, positive pressure assembly area to eradicate dust contamination
- Packing in ISO Class 7 Clean room to maintain cleanliness

Case Study

Fluid manifold block



Challenge:

Customer approached us at design stage with these requirements:

- Needed a lightweight, healthcare grade material
- Small diameter, interconnecting holes must be free from burrs and swarf
- Very tight positional tolerances

Material requested:

- Sustarin® C

Our solution:

- Sustarin® C met the physical requirements and passed the customer's in-house testing
- Three separate designs prototyped as the customer developed the product for optimum performance
- PPAP process for all prototype developments ensuring repeatability in production manufacture
- Endoscopic inspection developed and applied to 100% of the cross drilled holes
- 5 axis milling to achieve the positional accuracy

Chapter 4 | Delivery program

Our materials are available as semi-finished products in many different dimensions. In our brochure we show only an extract of the available dimensions. Due to the great variety, we cannot present our entire product range. Other dimensions are available on request! Please get in contact with us for further information.

	Polymer	Location	Product	Standard Colours ⁽¹⁾	Standard Dimensions ⁽²⁾
Medical Grades					
The Medical Grade (MG) portfolio is focused on medical devices for the risk classes I, IIa and IIb with less than 24 hours exposure. The use in implantable devices are not allowed. Therefore, those products are intended to be used for medical devices in accordance with the Regulation (EU) 2017/745, especially when it comes into direct short-term contact to the human body fluids and/or tissue respectively bones.					
SustaPEEK MG	PEEK	GER	Extruded sheets	Ⓝ ●	T: 6 – 60 mm W: 500/620 mm L: 1,000/2,000/3,000 mm
			Extruded rods	Ⓝ ● ● ● ● ● ● ● ●	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm
		USA	Extruded sheets	Ⓝ ●	T: 1/4" – 4" W: 24" L: 48"
			Extruded rods	Ⓝ ●	Ø: 1/4" – 6" L: 4 ft/8 ft
Sustason® PPSU MG	PPSU	GER	Extruded sheets	● ● ● ● ● ● ● ● ● ● ● ● ● ●	T: 20 – 60 mm W: 620 mm L: 1,000/2,000/3,000 mm
			Extruded rods	● ● ● ● ● ● ● ● ● ● ● ● ● ●	Ø: 20 – 90 mm L: 1,000/2,000/3,000 mm
		USA	Extruded sheets	● ● ● ● ● ● ● ● ● ●	T: 3/8" – 2" W: 24" L: 48"
			Extruded rods	● ● ● ● ● ● ● ● ● ●	Ø: 1/4" – 6" L: 4 ft/8 ft
SustaPEI MG	PEI	GER	Extruded sheets	Ⓝ	T: 20 – 60 mm W: 620 mm L: 1,000/2,000/3,000 mm
			Extruded rods	Ⓝ	Ø: 20 – 90 mm L: 1,000/2,000/3,000 mm
		USA	Extruded sheets	Ⓝ ● ● ● ● ● ● ● ● ● ●	T: 3/8" – 4" W: 24" L: 48"
			Extruded rods	Ⓝ ● ● ● ● ● ● ● ● ● ●	Ø: 3/8" – 6" L: 4 ft/8 ft
Sustason® PSU MG	PSU	GER	Extruded sheets	Ⓝ	T: 20 – 60 mm W: 620 mm L: 1,000/2,000/3,000 mm
			Extruded rods	Ⓝ	Ø: 20 – 90 mm L: 1,000/2,000/3,000 mm
ProMeX® MG EHS	PP ⁽³⁾	GER	CM sheets	○ ● ● ● ● ● ● ● ● ● ●	T: 8 – 120 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded rods	○ ● ● ● ● ● ● ● ● ● ●	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm
ProMeX® MG	PP ⁽³⁾	GER	CM sheets	Ⓝ	T: 8 – 120 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded rods	Ⓝ	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm

The right material according to your specification

The Healthcare industry has high standards for the final products and materials itself. With over 100 years of experience in plastic processing, we can precisely recommend the right material choice according to your specification. Our wide variety of colors, modifications, and special developments is probably unmatched on the market. Visit our website for more information.



	Polymer	Location	Product	Standard Colours ⁽¹⁾	Standard Dimensions ⁽²⁾
Healthcare Grades					
The Healthcare Grades (HG) are not intended to be used for medical devices in accordance with the Regulation (EU) 2017/745. Therefore, those products are not suitable for the manufacture of medical implants, critical components of medical devices with direct contact to the human body, fluids and/or tissue respectively bones, permanent oral or dental contact.					
SustaPVDF HG	PVDF	GER	Extruded sheets	Ⓝ	T: 8 – 100 mm W: 500/620 mm L: 1,000/2,000/3,000 mm
			Extruded rods	Ⓝ	Ø: 8 – 300 mm L: 1,000/2,000/3,000 mm
Polystone® PVDF HG	PVDF	GER	CM sheets	Ⓝ	T: 8 – 60 mm W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded sheets	Ⓝ	T: 1 – 50 mm W: 1,000/1,500 mm L: 2,000/3,000 mm
Polystone® P HG EHS	PP ⁽³⁾	GER	CM sheets	○ ● ● ●	T: 8 – 170 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded rods	○ ● ● ●	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm
Polystone® P HG HI	PP-B ⁽³⁾	GER	CM sheets	●	T: 8 – 170 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded rods	●	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm
Polystone® P HG	PP ⁽³⁾	GER	CM sheets	Ⓝ	T: 8 – 170 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded rods	Ⓝ	Ø: 10 – 100 mm L: 1,000/2,000/3,000 mm
Polystone® G HG	PE-HD	GER	CM sheets	Ⓝ ○	T: 8 – 170 mm ⁽⁴⁾ W: 1,000/2,000 mm L: 2,000/6,000 mm
			Extruded sheets	Ⓝ ○	T: 1 – 50 mm W: 1,000/1,500 mm L: 2,000/3,000 mm

Abbreviations: T = Thickness, W = Width, L = Length, CM = Compression Moulded

- (1) All colour illustrations are to be regarded as approximate only. The dimensions to the corresponding colours may defer. Depending on the material various colours are available – further customised colours upon request. Please contact us for further information, e.g. the colour specification similar to RAL.
- (2) The standard dimensions in sheets (thickness x width x length) and rods (diameter x length) are stated according to the international metric system of units. All materials from our USA location are stated in United States customary units. As part of our extensive service concept, we offer you various cutting and processing options. Please get in touch with us and ask us about our cut-to-size service.
- (3) According to DIN EN 15860:2018 microporosity in the centre of the cross-section may occur in semi-finished products made of Polypropylene (PP) and Polyoxymethylene (POM). The largest diameter or the widest part of the microporosity line(s) don't exceed 4%. The procedure for the determination and measurement of microporosity is described in Annex A of DIN EN 15860:2018. When semi-finished products subject to specific requirements, e.g., pressure tightness (microporosity) and/or dielectric strength, a test need to be administered by the user/processor. Please get in touch with us if you have special requirements for your application.
- (4) Skived sheets are available from 1 to 8 mm.

Colours

Ⓝ	Natural	○	White	●	Black	●	Blue	●	Green	●	Yellow
●	Orange	●	Red	●	Brown	●	Grey	●	Bone	●	Ivory

Chapter 5 | General notes

All the information contained in this brochure has been researched to the best of our knowledge. Nonetheless, errors cannot be completely precluded. For this reason, the information contained in the present brochure does not involve any kind of obligation or warranty/guarantee.

All application examples and use cases illustrated in this brochure have not been developed by Röchling itself, but by various customers of Röchling (after appropriate risk analysis by each customer, especially regarding end products that fall under the scope of the MDR Regulation (EU) 2017/745). Röchling cannot assess the compliance of the requested material for the intended purpose of the final product. Röchling exclusively manufactures the semi-finished products in accordance with the customer's or distributors ("Inverkehrbringer") specification. The customers are responsible for specifying the (technical) characteristics and specifications of the semi-finished products, providing us with these and ensuring that Röchling's semi-finished products are suitable for their intended use. It's the obligation of the customer to examine the suitability of our semi-finished products for the intended application and ensure that the end products are safe, provide the intended performance and function, and meet all legal and regulatory requirements. If the application of the end products requires official approval, certification, or any other authorization, the customer or distributor is responsible for obtaining these approvals, certifications, and/or authorizations and must carry out the necessary further tests and assessments or have them carried out.

The information in this publication and our declarations in connection with this publication do not constitute acceptance of a guaranteed or warranted characteristic of the semi-finished products. Röchling will be responsible for ensuring that the technical data as specified and confirmed by the customer are fulfilled by our corresponding semi-finished product. Guarantee declarations require Röchling separate express written declaration in order to be effective. The application examples do not exempt the user/ distributor from the obligation to examine and, if necessary, clarify the possibility of infringements of third-party rights, especially intellectual property rights. In all other respects, we refer to our General Terms and Conditions of sales (GTC of sales). These are available at:
www.roechling.com/gtc.

Application of Röchling Industrial materials

All our Röchling Industrial products including the ones described within this brochure are not suitable neither for medical devices in risk class III, for those with permanent oral or dental contact, for the manufacturing of medical implants nor direct contact of more than twenty-four (24) hours with body fluids and/or tissue respectively bones.

Additionally, the Healthcare Grades (HG) are not intended to be used for medical devices in accordance with the Regulation (EU) 2017/745. We do not advice or support use of our products in those specific medical and sensitive end-use applications.

Sterilisation and multiple use

For classification of the sterilisation 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.

As a general principle, it is incumbent upon the manufacturer of the final product to determine the suitability and the number of possible reprocessing cycles for a process. The data stated in the brochure are average values verified based on our statistical tests and controls. All information in this publication is based on current technical knowledge and experience. Due to the large number of possible influences during processing and application, it does not exempt the user/processor from carrying out their own tests and trials.

Different locations – Röchling Industrial USA

We have different production locations at Röchling Industrial. Therefore, all our products produced and supplied by our USA locations are stated explicit. There are different shapes and dimension available according to United States customary units. Besides, the local regulatory requirements and ASTM standards of the US market are considered. We are there, where you are! More information are on our US-based website:
www.roechling.com/us/industrial

Chapter 5 | Regulatory affairs/quality assurance

Quality Assurance

Certified quality management systems according to DIN EN ISO 9001:2015 and ISO 13485:2016 on different locations ensure that our products meet diverse customer requirements. The current versions of the certificates, clustered to locations and standard can be found on the website under
www.roechling.com/industrial/downloads.

The manufactured products are permanently subjected to defined quality tests in the different phases of production. Tests reports respectively inspections certificates according to EN 10204 can be provided upon request.

Regulatory Affairs

Regulatory Affairs means complying with legal regulations and guidelines with the aim of ensuring that the products to be used comply with the applicable laws and standards and that their safety, effectiveness and quality are guaranteed. To meet this requirement, Röchling provides product information at the customer's request with information containing the warranted characteristics, while the customer retain full regulatory responsibility for compliance of the final products.

What is meant by “Medical Grade Plastics”?

The legally unprotected term “Medical Grade Plastics” (MGP) refers to polymeric plastics and refined plastic preparations that are intended by manufacturers for the production of end products in the following areas of application:

- Medical devices according to Regulation (EU) 2017/745
- In-vitro diagnostics according to Regulation (EU) 2017/746
- Pharmaceutical primary packaging of different regulations

What are the regulatory requirements for Medical Grade Plastics made by Röchling?

There are currently no EU or US directives or standards which the term “Medical Grade Plastic” materials unambiguously define or describe which specific properties plastic materials must have in order to manufacture medical products from them.

The VDI Guideline 2017 offers a clear definition of the term MGP and specifies the requirements that are expected in particular for applications like medical devices, pharmaceutical packaging and in-vitro diagnostics:

- the defined or agreed scope of services of an MGP product in relation to the regulatory requirements (biological, chemical, sterilisation, material-specific tests, packaging),
- the and about the delivery agreements that are to be made individually between the parties involved (manufacturer, supplier, customer...) in medical technology,
- requirements for recipe consistency,
- the security of delivery,
- a change management.

What benefit do Röchling materials offer?

- Well established product portfolio of Medical Grade (MG) and Healthcare Grade (HG) plastics on the market
- Wide range of dimensions, shapes, and colours – mostly available from stock
- Biocompatibility tests according to ISO 10993-5 and USP-VI testing (optional) – tested by resin supplier and/or additionally on semi-finished products (MG)
- 100% traceability across the manufacturing process to the raw material lot used
- Certified according to DIN EN ISO 9001:2015 and/or ISO 13485:2016 (differ from location)
- Documentation of all relevant processes respectively product information
- Conformity with FDA (CFR 21 Code of Federal Regulations – Food and Drugs) if applicable, to achieve the necessary requirements
- Conformity of our MG products with Annex I, Chapter II, Paragraphs 10.4.1-3 and 10.13 the regulation (EU) 2017/45 (MDR) – for European locations, to achieve the necessary requirements
- In accordance with VDI 2017 guideline, including but not limited to the consistency of the recipe (including evaluation) and the manufacturing process as well as the change management – for European locations
- Appropriate storage & packaging, pest control...

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