Röchling

Industrial

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 200 years. We transform the lives of people every day with our customised plastics: they reduce the weight of cars, make medication packaging more secure and improve industrial applications. Our workforce of around 11,700 people is located in the places where our customer are – in more than 90 locations in 25 countries. The Group's three divisions generated joint annual sales of 2.603 billion euros in 2022.

Content

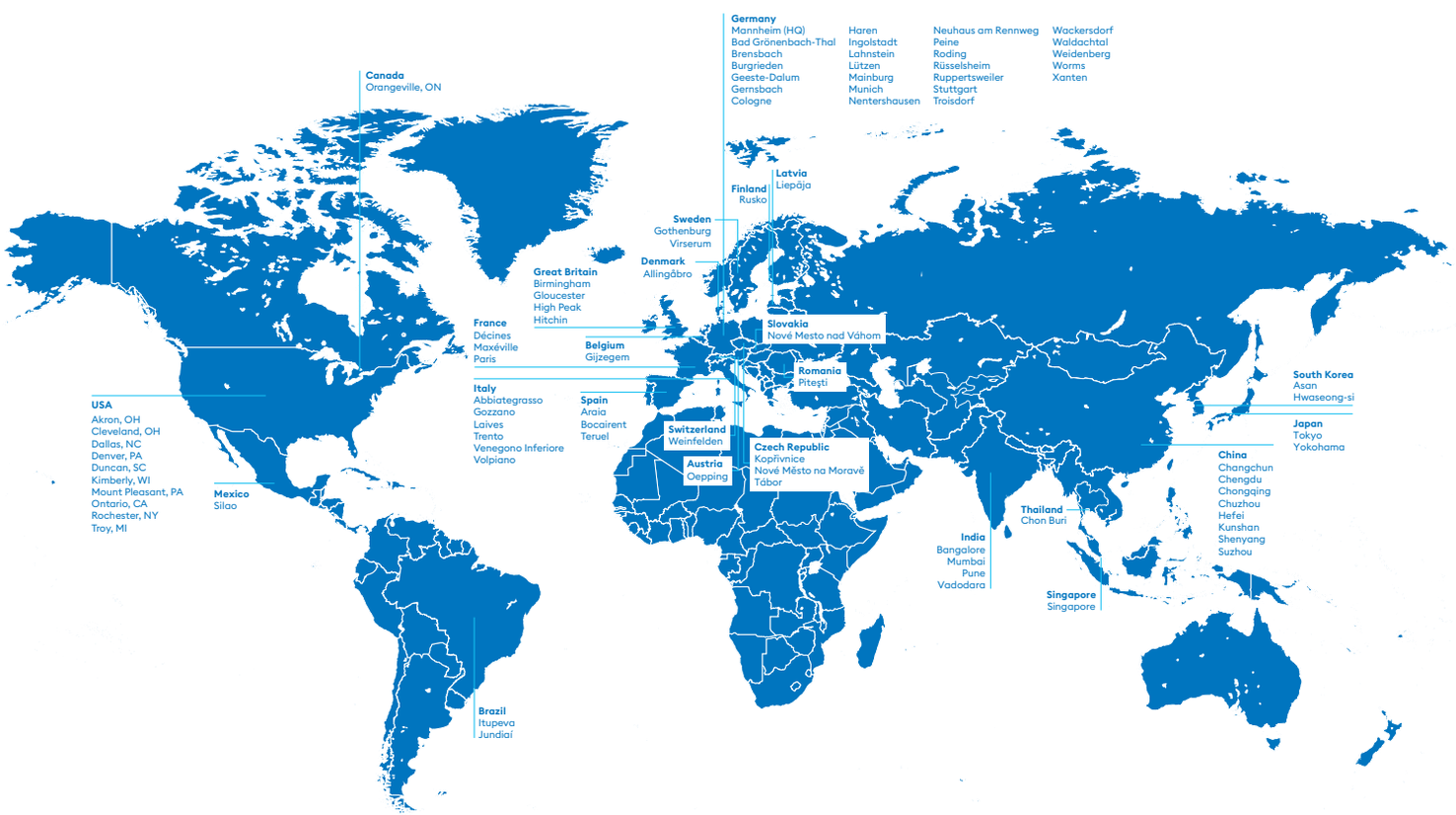
Röchling Industrial

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.



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 and ISO 13485:2016 ensure that our healthcare 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:

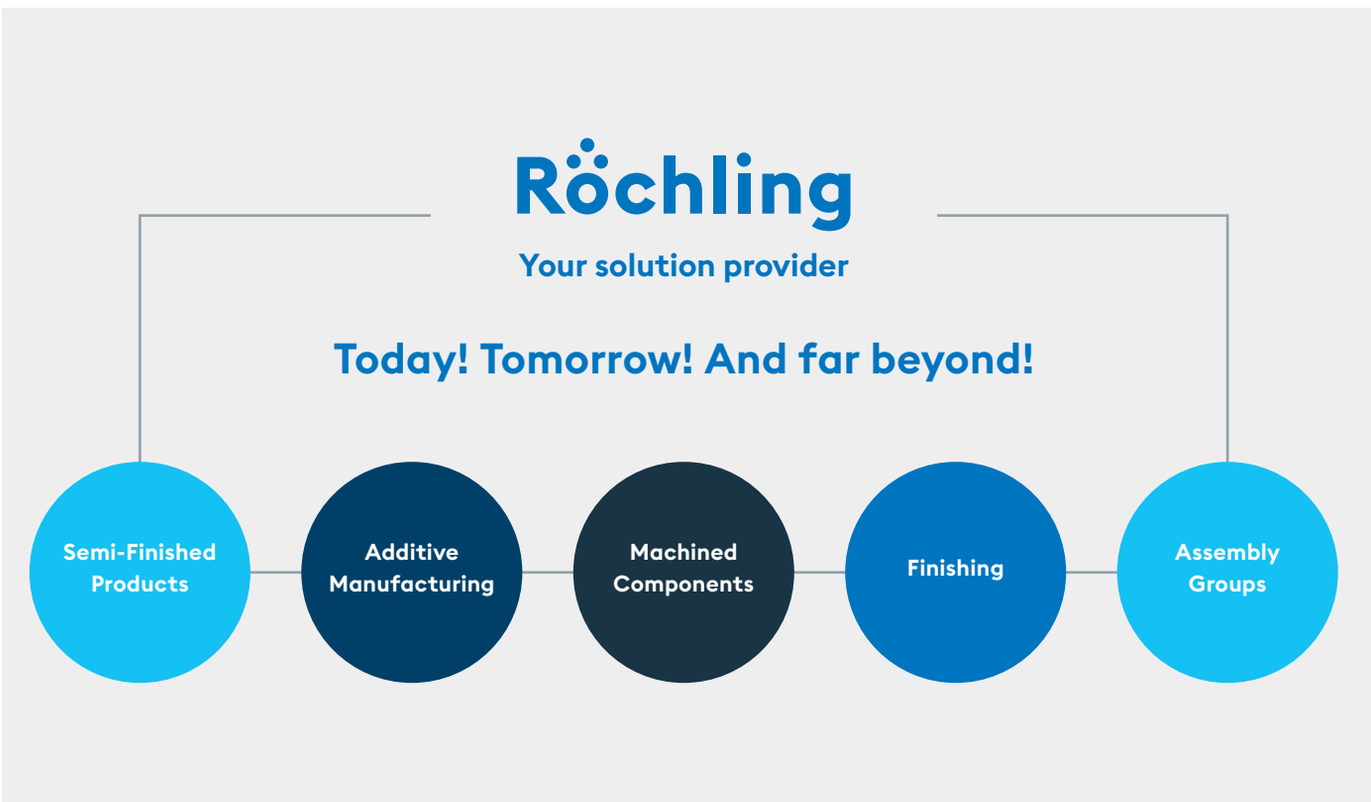
- Assisting with the configuration and design of your components
- Support from the selection of suitable materials to the final product
- From prototyping to series production

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.

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.

With this wide range of materials, we support the different requirements of the Healthcare industry. Our qualified and proven materials include for example:

- SustaPEEK MG
- Sustason® PPSU MG
- SustaPEI MG
- ProMeX® MG
- Polystone® P HG
- Sustarin® C HG
- TroBloc® M
- Fibracon® PTFE
- Durostone®

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 advise you on the selection of suitable materials specifically for your applications/needs.

Biocompatibility (ISO 10993-5, USP VI)

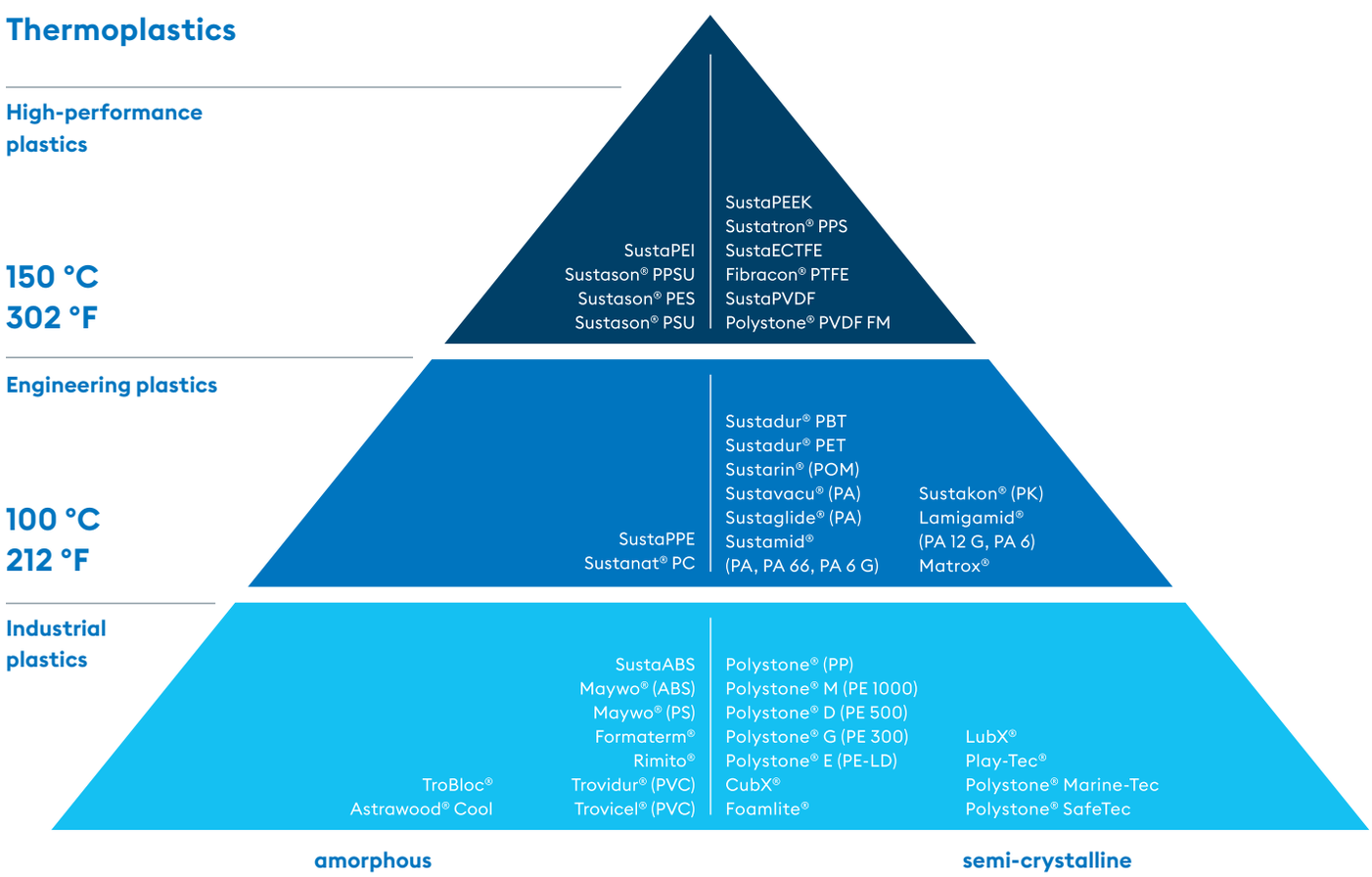
Sterilisation resistance

Chemical resistance

Impact resistance

Temperature resistance

Thermoplastics



Medical & Healthcare grades – product overview

List of semi-finished products by Röchling Industrial for medical & healthcare applications (with less than 24 hours exposure) considering the requirements of biocompatibility, MDR and FDA compliance as well as sterilisation resistance. Our Röchling Industrial portfolio is not suitable for neither the manufacture of medical implants, critical components of medical devices, permanent oral nor dental contact. (1)

			Biocompatibility		Compliance		Sterilisation resistance				
	Polymer	Location	ISO 10993-5	USP Class VI	MDR(2)	FDA(2)	Hot Steam [134°C]	Hot Air [180°C]	Ethylene oxide [60°C]	Plasma [45°C]	Gamma rays(3) [RT]
Medical Grades(1)											
The Medical Grade (MG) portfolio is focused on ISO 10993 Type A "medical" applications with less than 24 hours exposure. It is intended to be used for medical application in accordance with the Regulation (EU) 2017/745, especially when it comes to direct 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	USA	✓	✓	✓	✓	> 2,000(7)	●	●	●	●
ProMeX® MG EHS	PP-H	GER	✓(4)	✓(4)	✓	✓	> 500(8)	–	○	◑	○
ProMeX® MG	PP-H	GER	✓(4)	✓(4)	✓	✓	–	–	○	◑	–
Healthcare Grades(1)											
The Healthcare Grades (HG) 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. The Healthcare Grades (HG) are not intended to be used for medical application in accordance with the Regulation (EU) 2017/745.											
Polystone® P HG EHS	PP-H	GER	✓(4)	✓(4)		✓	> 500(9)	–	○	◑	○
Polystone® P HG HI	PP-H	GER					○	–	○	◑	–
Polystone® P HG	PP-H	GER	✓(4)	✓(4)		✓	–	–	○	◑	–
Sustarin® C HG	POM-C	GER	✓(10)	✓(10)		✓	○	–	◑	◑	○

Industrial Grades

- Sustason® PSU (PSU)
- SustaPPE (PPE)
- SustaPVDF (PVDF)
- Polystone® P (PP-H)
- Polystone® P ortho HI (PP-H)
- Polystone® P ortho (PP-H)
- Polystone® G (PE-HD)
- Polystone® E (PE-LD)
- TroBloc® M (TroBloc)
- Formaterm® ABS/TPE (ABS)
- Fibracon® PTFE

Composites

- Durostone® UPM
- Durostone® EPM
- Durostone® EPC
- Glastic®

For more specifications and details get in touch with us!

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) Responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product/end product.
(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 cause changes to technical properties and colour in 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 17665-1:2006-11 "Test report for long term reprocessing stability study" permormed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AA1793, Version: V4, Date: 26.06.2023.
(6) According to DIN EN ISO 17665-1:2006-11 "Test report for long term reprocessing stability study" permormed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AA1794, Version: V4, Date: 26.06.2023.
(7) According to DIN EN ISO 17665-1:2006-11 "Test report for long term reprocessing stability study" permormed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AA1795, Version: V4, Date: 26.06.2023.
(8) Röchling Industrial, Quality Investigation Report (QIR), Titel: Sterilisationsprozess von thermoplastischen Kunststoffen, Document No.: QIR_TH_2022-05, Rev.: 000, Date: 08.09.2022
(9) According to DIN EN ISO 17665-1:2006-11 "Test report for long term reprocessing stability study" permormed by the accredited laboratory senetics healthcare group GmbH & Co. KG (Hardtstr. 16, 91522 Ansbach, Germany), Document No.: 22AA1790, Version: V3, Date: 26.06.2023.
(10) Based solely on information published by the resin supplier. For more information get in touch with us.

More information:

Biocompatibility

Medical & Healthcare 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 application 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

There are test results for biocompatibility according to ISO 10993-5 and the USP Class VI available for most of the medical & healthcare products from Röchling Industrial. The tests were conducted either from the raw material supplier or on the semi-finished product manufactured by Röchling.

DIN EN ISO 10993-5

The scope of the biocompatibility tests as per ISO 10993-5 on the specific nature of the physical contact, as well as on the duration of contact. Within the scope of selecting suitable material for a medical-technical application, not only the technical requirements have to be considered. It is necessary to ensure the material is compatible with the human organism.

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

Responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product/end product.

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

Machining competence

How your part is realised

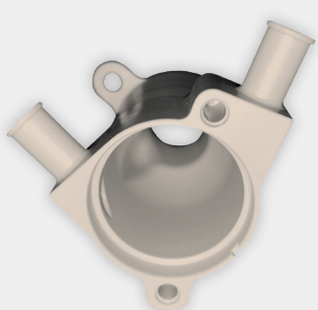
Components are required fulfilling the highest demands in terms of functionality, design and safety. As a leading plastic processor, we know the possibilities of different materials. With our comprehensive range of machining and production possibilities we realise components that will function optimally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

Turning

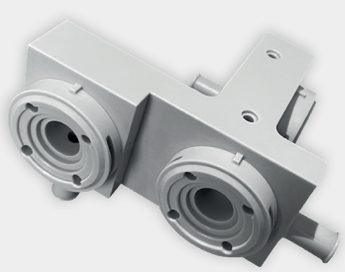
Material used:
Sustarin® C HG, black

Turning and milling



Material used:
SustaPEEK MG, natural

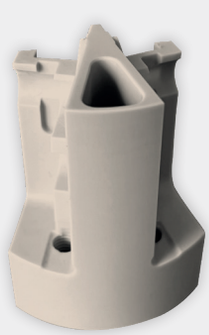
Milling



Material used:
Polystone® P HG, grey

Material used:
SustaPEEK MG, green

Material used:
Sustason® PPSU MG, black



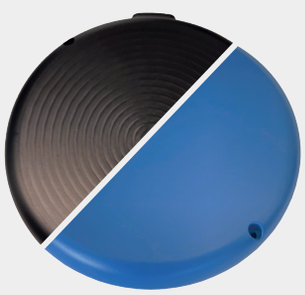
Material used:
SustaPEEK MG, natural

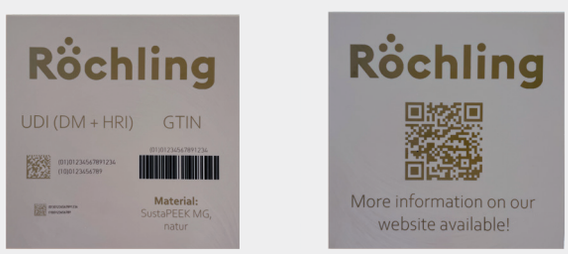
Note: HG = Healthcare Grade | MG = Medical Grade
For further explanation see pages 7 and 8.

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.

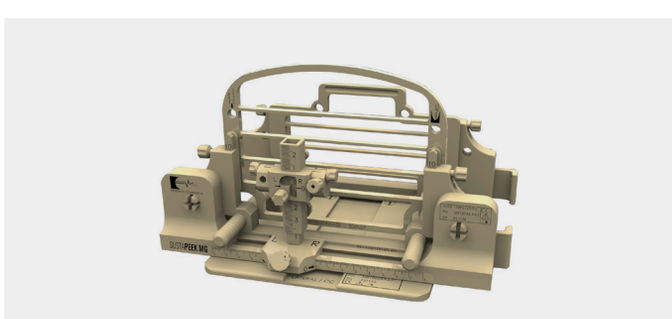
Marking: Individual parts can be marked UDI compliant (Datamatrix + HRI) as well as with any logos, emblems, serial-/article number, GTIN or construction codes. For this process laser marking and printing are available.





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

Materials and parts for 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

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

Material used:

- 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

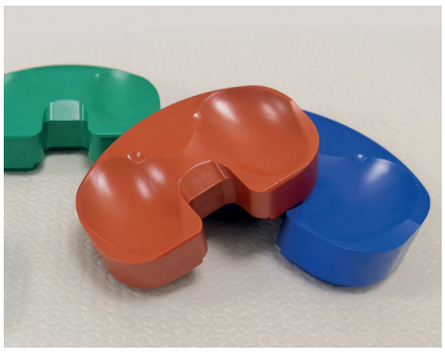
Product examples

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

Material:

- TroBloc® M



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:

- Sustason® PPSU MG

Case Study

Handle for surgical instruments

Material used:

- SustaPEEK 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

Challenge:

Customer approached us with these requirements:

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

Your advantages

- Long-lasting and low maintenance: due to excellent chemical resistant
- Economic production processes
- Increased sealing efficiency
- Reduced risk of damage to critical (riser) equipment

Materials and parts for 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.

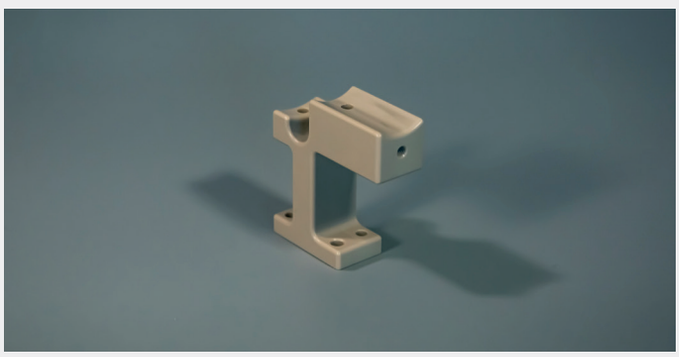
The Healthcare Grades (HG) would be a suitable solution for such requirements, especially when it doesn't come to direct contact to the human body fluids and/or tissue respectively bones. For further explanation see pages 7 and 8.

Typical parts include:

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

Case Study

Alignment segment for mass spectrometry



Challenge:

Customer approached us with these requirements:

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

Material used:

- 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

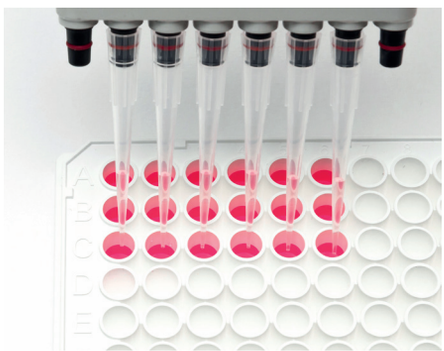
Product examples

Centrifuge applications

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

Typical material:

- Polystone® P HG HI (black)



Manifold for cell cultivation and thermal expansion proper

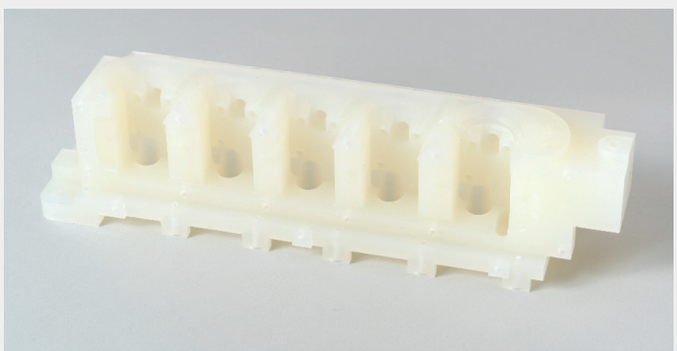
- Components require excellent chemical resistance due to multiple experiments
- Good stability

Typical material:

- Polystone® P HG

Case Study

Reservoir clamp main body



Challenge:

Customer approached us with these requirements:

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

Material used:

- 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

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

Materials and parts for 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) would be a suitable solution for such requirements, especially when it doesn't come to direct 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

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 used:

- Sustarin® C HG

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

Product examples

Pharmaceutical production

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

Typical material:

- Sustarin® C HG
- Sustadur® PET

Chromatography applications

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

Typical material:

- Polystone® P HG

Case Study

ESD and anti-static products for tablet manufacturing

Challenge:

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

Materials used:

- 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

Materials and parts for 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. Therefore we offer design and material advice, prototype production, demanding geometries and bespoke quality controls.

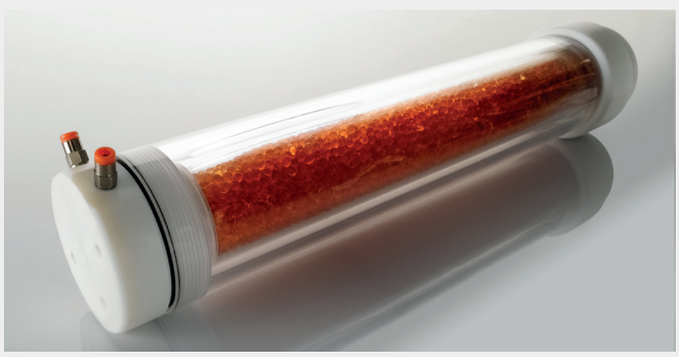
The Healthcare Grades (HG) would be a suitable solution for such requirements, especially when it doesn't come to direct contact to the human body fluids and/ or tissue respectively bones. For further explanation see pages 7 and 8.

Typical parts include:

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

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

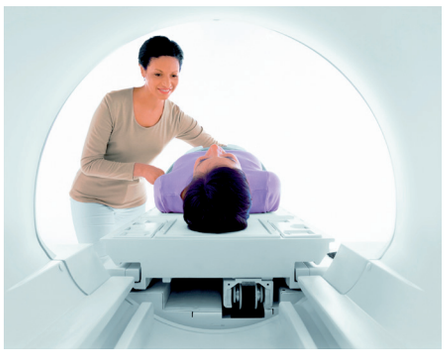
Materials used:

- 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

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:

- Durostone®

Wear profiles for drug analysis

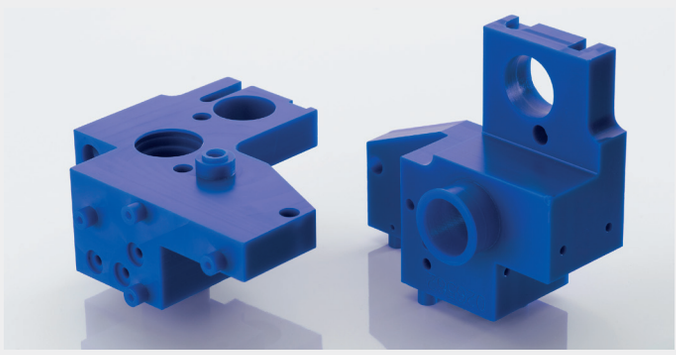
- Chemically resistant and good wear properties
- Good performance under high temperature

Typical material:

- Sustadur® PET

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 used:

- Sustarin® C HG

Our solution:

- Sustarin® C HG met the physical requirements and passed the customer's in-house testing for compatibility
- 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

Delivery programme – semi-finished products

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 ISO 10993 Type A "medical" applications with less than 24 hours exposure. It is intended to be used for medical application in accordance with the Regulation (EU) 2017/745, especially when it comes to direct 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	USA	Extruded sheets	Ⓝ ● ● ● ●	T: 3/8" – 4" W: 24" L: 48"
			Extruded rods	Ⓝ ● ● ● ●	Ø: 3/8" – 6" L: 4 ft/8 ft
ProMeX® MG EHS	PP-H[3]	GER	CM sheets	○ ● ● ●	T: 8 – 60 mm W: 1,000/1,250/2,000/2,500 L: 2,000/3,000/4,000/6,000
			Extruded rods	○ ● ● ●	Ø: 10 – 180 mm L: 1,000/2,000/3,000 mm
ProMeX® MG	PP-H [3]	GER	CM sheets	Ⓝ	T: 8 – 60 mm W: 1,000/1,250/2,000/2,500 L: 2,000/3,000/4,000/6,000
			Extruded rods	Ⓝ	Ø: 10 – 180 mm L: 1,000/2,000/3,000 mm
Healthcare Grades					
The Healthcare Grades (HG) 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. The Healthcare Grades (HG) are not intended to be used for medical application in accordance with the Regulation (EU) 2017/745.					
Polystone® P HG EHS Polystone® P HG HI Polystone® P HG	PP-H[3]	GER	CM sheets	○ ● ●	T: 8 – 180 mm[4] W: 1,000/1,250/2,000/2,500 mm L: 2,000/3,000/4,000/6,000 mm
			Extruded rods	○ ● ●	Ø: 10 – 300 mm L: 1,000/2,000/3,000 mm
Sustarin® C HG	POM-C	GER	Extruded sheets	Ⓝ ● ● ● ● ● ● ●	T: 6 – 200 mm W: 620/1,000/1,250 mm L: 1,000/2,000/2,500/3,000 mm
			Extruded rods	Ⓝ ● ● ● ● ● ● ●	Ø: 5 – 210 mm L: 1,000/2,000/3,000 mm

The right material for your application

We are happy to advise you on selecting the right materials for your particular application. Having specialised in the processing of plastics for more than 100 years, we know precisely which material to recommend for your requirements. The wide variety of modifications and special developments is also probably without equal on the market. You find more information on our website.

	Polymer	Location	Product	Standard Colours[1]	Standard Dimensions[2]
Industry Quality					
Our product portfolio is completed by our wide range of industrial materials. Depending on the application and the need they can be additionally used where no specific certifications are required. Please get in contact with us for more information.					
Sustason® PSU SustaPPE SustaPVDF	PSU PPE PVDF	GER	Extruded sheets	Ⓝ	T: 6 – 150 mm W: 620/1,000/1,250 mm L: 1,000/2,000/2,500/3,000 mm
			Extruded rods	Ⓝ	Ø: 5 – 300 mm L: 1,000/2,000/3,000 mm
Polystone® P Polystone® G Polystone® E	PP-H[3] PE-HD PE-LD	GER	CM sheets		T: 8 – 200 mm[4] W: 1,000/1,250/2,000/2,500 mm L: 2,000/3,000/4,000/6,000 mm
			Extruded sheets		T: 1 – 50 mm W: 1,000/1,220/1,500/2,000 mm L: 1,000/2,000/2,440/3,000/4,000 mm
			Extruded rods		Ø: 10 – 300 mm L: 1,000/2,000/3,000 mm
TroBloc® M	TroBloc	GER	CM sheets	○	T: 2.5 mm W: 1,220 mm L: 2,440/3,050 mm
Fibracon®	PTFE	UK	CM rods	○	Ø: max. 500 mm L: 50 – 200 mm
			CM tubes	○	Ø: max. 1,250 mm L: 50 – 150 mm
Composites					
Besides our thermoplastic materials our extensive range of semi-finished products and machined components is completed by our composite materials. Because of the material properties it could be taken into consideration in some defined areas within the Healthcare industry.					
Durostone® UPM Durostone® EPM Durostone® EPC		GER FRA USA	CM sheets	○ ● ● / Ⓝ ● ● ●	T: 0.5 – 140 mm W: max. 2,000 mm L: max. 5,000 mm
Glastic®		GER USA	CM sheets	○ ● Ⓘ	T: 0.8 – 150 mm W: 914/1,255 mm L: 1,828/2,445 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

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. 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. This work is protected by copyright. All rights, including those of translation, reprint and duplication and/or parts thereof are reserved for Röchling Industrial.

The information in this publication and our declarations in connection with this publication do not constitute acceptance of a guaranteed or warranted characteristic. Guarantee declarations require our separate express written declaration in order to be effective. We reserve the right to adapt the product to technical progress and new developments. Please do not hesitate to contact us if you have any questions or if you experience any specific application problems. Together with the customer it is our goal to find suitable solutions for the requested requirements.

Our application recommendations do not exempt the user/processor from the obligation to examine and, if necessary, clarify the possibility of infringements of third-party rights. In all other respects, we refer to our General Terms and Conditions (GTC). 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 for the manufacture of medical implants, critical components of medical devices, permanent oral or dental contact, or 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 application in accordance with the Regulation (EU) 2017/745. We do not recommend or support use of our products in those specific medical and sensitive end-use applications.

Responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product/end product.

Sterilisation and multiple use of medical products

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 product to determine the suitability and the number of possible reprocessing cycles for a process.

The data stated above are average values verified on the basis of 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. Responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product respectively end product. Suggested uses do not constitute an assurance of suitability for the recommended purpose.

Different locations – Röchling 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!

Regulatory affairs/QA

Certified quality management systems according to DIN EN ISO 9001:2015 and ISO 13485:2016 ensure that our products meet diverse customer requirements. The actual version of the certificates can be found on the website under **www.roechling.com/industrial/downloads**. The manufactured products are permanently subjected to different quality tests in all phases of production. Tests reports respectively inspections certificates according to EN 10204 can be provided upon request.

Regulatory Affairs

The term "regulatory affairs" can be understood as the process of fulfilling legal and/or regulatory requirements that are necessary to obtain official approval and of providing evidence. To meet this requirement, Röchling creates product information at the customer's request.

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 2017 guideline offers a clear definition of the term medical grade and specifies the requirements that are to be expected especially for plastics for use in medical products, 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),
- requirements for recipe consistency,
- the security of delivery,
- a change management
- and about the delivery agreements that are to be made individually between the parties involved (manufacturer, supplier, customer…) in medical technology.

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
- 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
- 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…

Röchling

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