

## Röchling's line of medical grade plastics is now ISO 13485:2003 certified!

**ISO 13485:2003** NEW

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

Röchling Engineering Plastics is the only manufacturer in North America to be ISO 13485:2003 certified that supplies our broad product offering of engineering plastic stock shapes to the life science industry.

ISO 13485 is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacturing of medical devices including:

- controls to ensure product safety
- risk management activities
- inspection and traceability
- documentation and validation of processes
- verification of the effectiveness of corrective and preventive actions

In addition to our new ISO 13485 certification we also offer ISO 10993 compliancy, and USP Class VI compliancy or certification

### Röchling: your preferred source for Medical Grade Plastics!

- SustaPEEK MG
- SustaPEI MG (Ultem®)
- Sustason PPSU MG (Radel® R)
- Sustanat PC MG (Polycarbonate)
- Sustarin® C MG (Acetal)
- Sustason PSU MG (Polysulfone)
- Polystone® P MG (Polypropylene)
- SustanatPPO MG (Noryl)



*The values indicated result from numerous measurements for an approximation of the values and are to our best knowledge. They serve as information about our products and are presented as a guide to choose from a range of materials. This however does not include an assurance of specific properties or the suitability for particular application purposes that are legally binding. Since the properties also depend on the dimension of the semi-finished products and the degree of crystallization (e.g. nucleating by pigments), the actual values of the properties of a particular product may differ from indicated values.*

Röchling Engineering Plastics offers the most comprehensive product line in the USA and Canada including:

- |                              |                  |
|------------------------------|------------------|
| Polystone® M (UHMW-PE)       | Sustamid® Nylon  |
| Polystone® P (Polypropylene) | Sustarin® Acetal |
| Polystone® G (HDPE)          | Susta HPM's      |



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