# Product Information
## Declaration to Biocompatibility (MEDICAL GRADE)

| SUSTAPEEK MG | SUSTASON PPSU MG |
|---|---|
| ( **VICTREX™ PEEK 450G** ) | (Solvay **Radel® R** PPSU) |

Non-binding evaluation of semi-finished medical devices produced by Röchling Sustaplast SE & Co.KG based on the intended nature/duration of contact:

| Nature of body contact (based on DIN EN ISO 10993-1) | Contact duration | ISO 10993-5 | ISO 10993-10 |
|---|---|---|---|
| Intact skin | A (<24h) | X | O |
| Mucosal membrane | A (<24h) | X | O |
| Breached or compromised surface | A (<24h) | X | O |
| Blood path, indirect(1) | A (<24h) | X | O |
| Tissue/bone/dentin(1) | A (<24h) | X | O |
| Circulating blood(1) | A (<24h) | X | O |

(1) It is pointed out to manufacturers that every application must be carefully tested and that the manufacturer itself is responsible for ensuring all required tests (in particular according to ISO 10993) are carried out for the intended use. In the EU medical products may only be placed on the market if they have received a CE marking for the intended procedure and only if they otherwise meet all requirements of relevant legislation.

X = The semi-finished product is subjected to random testing
O = Semi-finished product is not tested. Assumption of suitability based on the data provided in the product information of the raw material producer.

### Test in compliance with DIN EN ISO 10993-5

The extruded medical grade semi-finished products listed above, manufactured by Röchling Sustaplast SE & Co.KG (Germany), meet the criteria of DIN EN ISO 10993-1 "Biological evaluation of medical devices Part 5: Test for cytotoxicity".
In part the raw material producers have carried out tests on the raw materials (Granules) used pursuant to DIN EN ISO 10993-1 (Table A.1 – Biological Risk Assessment) within the framework of the biocompatibility evaluation.
As a rule this information is available on the websites of the raw material producers.

### Risk process / incoming goods

Our risk management process ensures that within the framework of the incoming goods inspection of the raw material the cytotoxicity test (DIN EN ISO 10993-5) is carried out by an accredited institute on a representative delivery lot of the semi-finished product produced with the raw material.
Only raw materials and test items with the result “not cytotoxic” pass the internal qualification, which is the condition for release of the raw material. Only released raw material batches are used in the manufacturing process of medical grade semi-finished products.

The cytotoxicity test is not part of a continuous production control.

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## Manufacturing process

The recommendations of the raw material producers are taken into account during the manufacturing and handling process. In order to reduce the internal stress after extrusion, the semi-finished products are subjected to an annealing process.

## Identification and traceability

Our medical grade semi-finished products are marked and fully traceable through their batch number up to the used raw material lot.

## Colour and additives

The coloured products contain pigments that´s conform to specific FDA regulations and might also contain other additives that, according to the data of our raw material suppliers, comply with the applicable FDA requirements for food contact materials. There could be specific FDA provisions with regard to the use for food contact – we request you comply with the data of the raw material suppliers.

No additional additives, plasticizers or processing agents are used in the manufacturing process.

## Final processing

On request the semi-finished products can be processed and cut in our cutting center. Planning, sawing and milling operations are carried out without the use of cooling lubricants. This product information encompasses the working steps planning, sawing and milling – all without the use of cooling lubricants.

A cooling lubricant is used for grinding. The impact of the cooling lubricant used on the biocompatibility properties has not been tested and must be re-evaluated in the downstream processing steps.

## Exclusions

Our Medical Grade semi-finished products are not intended for the manufacture of 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 / bones.

The processors and marketers of medical devices are advised that any intended application must be carefully examined. In the EU, medical products may only be placed on the market if they have been CE-marked in the procedure provided for them and also fulfill all the requirements of the respective relevant legislation. The sole responsibility for the evaluation of the end product for the intended use and

compliance with the applicable requirements lies solely with the manufacturer / marketer of the respective product / end product.

Röchling Sustaplast SE & Co. KG
Quality Management

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