

## Product information

# Medical Device Regulation (EU) 2017/745

## Annex I, Chapter II, paragraphs 10.4.1-3 and 10.13

This document is to confirm that the substances within the scope of the EU Medical Device Regulation (MDR) EU 2017/745 (CMR (carcinogenic, mutagenic or toxic to reproduction), endocrine disrupting and animal origin substances as well as phthalates), have not been intentionally added or used in the manufacturing processes of the listed Medical Grade (MG) products below:

Products		
SustaPEEK MG black	SustaPEEK MG natural	Sustason® PPSU MG black
Sustason® PPSU MG blue	Sustason® PPSU MG brown	Sustason® PPSU MG green
Sustason® PPSU MG grey	Sustason® PPSU MG red	Sustason® PPSU MG yellow

**Color codes:**

SUSTASON PPSU MG, BK 937 Black  
 SUSTASON PPSU MG, BU 1027 Blue  
 SUSTASON PPSU MG, BN 1164 Brown  
 SUSTASON PPSU MG, GN 1007 Green  
 SUSTAPEEK MG natural

SUSTASON PPSU MG, GY 1037 Grey  
 SUSTASON PPSU MG, NT 15 Natural (Bone)  
 SUSTASON PPSU MG, RD 1018 Red  
 SUSTASON PPSU MG, YL 1337 Yellow  
 SUSTAPEEK MG black

Substances within the scope of the EU MDR (EU) 2017/745 Annex I, Chapter II, Sections 10.4.1a & b:

- (a) Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or
- (b) Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (Biocidal Products), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

Substances as outlined in Sections 10.4.1 a & b are not contained at concentrations above 0.1% (w/w).

This information relies on manufacturer data's given by our suppliers. However, we do not conduct any analyses to determine if any impurities exist. No additional additives, plasticizers, animal origin substances or processing aids are added in the manufacturing process. We do not use any recycled, reconstituted, regrind, recovered or reprocessed resin in any of the production for these items. The seller of these parts and articles made out of the above mentioned items have to take



full responsibility regarding applicable legal requirements, as we do not supply a device, only an intermediate product.

The current candidate list of Substance of Very High Concern (SVHC) can be found:

<https://echa.europa.eu/candidate-list-table>, with substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health specified as “Endocrine disrupting properties (Article 57(f) – human health)”

Advice: This document has been printed automatically and is valid without any signature. This product information serves alone for informative purposes. Warranties, assurances and guarantees cannot be derived from this.

Important: This information is accurate as of the date of issue based on the most recent version of any applicable manufacturer's instructions, regulations or standards, unless otherwise stated above. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. The suitability of Röchling Industrial Lahnstein SE & Co. KG products in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final product to assess and determine the suitability of all components to ensure that the final product is safe for its intended use (Fit for Use) as well as all applicable legal or other regulatory requirements.

### Quality Management

Röchling Industrial Lahnstein SE & Co. KG

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