Informace o výrobku

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), updated through ATP 18 (EU) 2021/849, have not been intentionally added or used in the manufacturing processes of the listed Medical Grade (MG) products below:

Výrobky		
SustaPEEK MG modrý BL	SustaPEEK MG přírodní	SustaPEEK MG zelená GN
SustaPEEK MG černý	SustaPEEK MG červená RD	SustaPEEK MG žlutá YL
SustaPEI MG přírodní	Sustason® PPSU MG bone NT15	Sustason® PPSU MG hnědá
Sustason® PPSU MG modrý	Sustason® PPSU MG oranžová	Sustason® PPSU MG zelená
Sustason® PPSU MG černý	Sustason® PPSU MG červená	Sustason® PPSU MG šedý
Sustason® PPSU MG žlutá	Sustason® PSU MG přírodní	

Please be advised that these grades are compliant with the referenced sections of the regulation, as well as the raw materials used in our formulations.

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 biocompatibility of the above-mentioned products was tested by means of a cytotoxicity test in accordance with ISO 10993-5 on semi-finished products. Ubiquitous trace impurities (e.g., due to technical and natural conditions) cannot be completely ruled out. We reserve the right to update/revise the statements made here if updated information from our suppliers on the raw materials used becomes available.

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.

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)”

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Röchling Industrial Lahnstein SE & Co. KG
Sustaplast-Str. 1 • 56112 Lahnstein/DE • Tel. +49 2621 693-0
info.lahnstein@roechling.com • www.roechling.com/industrial/lahnstein