

ABSENCE DECLARATION RoHS

Date.: 09. February 2024 ⁽¹⁾

Version 5.0

Products: stock shapes

PC LSG natural

PEI LSG natural, black

PEEK Classix white

PEEK CA30 LSG

PEEK LSG natural, black, yellow, red, green, blue

PEEK LSG + FG natural, black

PP-H LSG natural

PPSU LSG all colours

PSU LSG natural

To the best of our knowledge, we herewith confirm that the substances cadmium (Cd), lead (Pb), mercury (Hg), hexavalent chromium [Cr(VI)], polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP), regulated by:

- the **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances (**RoHS**) in electrical and electronic equipment, as amended up to and inclusive of the Commission Delegated Directive (EU) 2024/232,
- Annex II of **Directive 2000/53/EC** of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (ELV) as amended up to and inclusive of the Commission Directive 2023/544,
- **Chinese legislation** – Order n° 32, Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, published on 21 January 2016,

are neither intentionally introduced⁽²⁾ during the production of the raw materials nor during the manufacture of the above stock shapes.

Since the presence of the above mentioned substances cannot reasonably be expected, with the exceptions as mentioned below, BBC Cellpack Technology AG does not systematically check their absence in its stock shapes by testing.

All statements, technical information, recommendations, and advice are for informational purposes only and are not intended and should not be construed as a warranty of any type or term of sale. The reader, however, is cautioned that BBC Cellpack Technology AG does not guarantee the accuracy or completeness of this information and it is the customer's responsibility to test and assess the suitability of the products in any given application or for use in a finished device.

The products of BBC Cellpack Technology AG should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days*), or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*), or as critical components of medical devices that are essential to the continuation of human life.

*: "30 days" applies to PEEK Classix white only.

BBC Cellpack Technology AG is not a medical device manufacturer and the information herein does not constitute any express or implied warranties or representations whatsoever, including, but not limited to, all warranties provided for by any applicable law, any implied warranty of merchantability, of fitness for a particular purpose, any warranty against hidden defects or redhibitory defects or vices, or that the products of BBC Cellpack Technology AG are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration of or continuation of a bodily function important to the continuation of human life.

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- 1) This statement expires in case of regulatory or compositional changes.
 - 2) "Intentionally introduced" means "deliberately utilised in the formulation of a material to facilitate manufacture or to provide a specific characteristic, appearance or quality".