

<b>COMPANY STATEMENT</b>	<b>Nanomaterials</b> As defined within the EU Commission Recommendation 2022/3689/EU
<b>SUPPLIER</b>	Invibio Ltd
<b>PRODUCT NAME</b>	<p><b>PEEK-OPTIMA™ Natural grades:</b> LT1, LT2, LT3 Granules, stock shapes and fine powder;</p> <p><b>PEEK-OPTIMA™ Reinforced grades:</b> LT1CA30, LT1DA30 Granules and Stock shapes;</p> <p><b>PEEK-OPTIMA™ Ultra-Reinforced grades:</b> LT3PPT unidirectional tape</p> <p><b>PEEK-OPTIMA™ Image Contrast grades:</b> LT16BA, LT120BA, LT215BA, LT320BA Granules and stock shapes</p> <p><b>PEEK-OPTIMA™ HA Enhanced grades:</b> LT120HA Granules and stock shapes</p> <p><b>PEEK-CLASSIX™ grades:</b> BC1, BC2, BC3, BC1-WH<sup>2</sup>, BC2-WH<sup>2</sup>, BC3-WH<sup>2</sup></p>

This document is to confirm that nanomaterials<sup>1</sup> have not been generated in the manufacturing process, nor intentionally added to the Invibio products detailed above.

**Notes**

1. Nanomaterials as defined within the EU Commission Recommendation 2022/3689/EU:

*'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:*

- (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;*
- (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;*
- (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.*

*In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.*

*However, a material with a specific surface area by volume of < 6 m<sup>2</sup>/cm<sup>3</sup> shall not be considered a nanomaterial.*

2. The PEEK-CLASSIX™ grades BC1-WH, BC2-WH, BC3-WH contain titanium dioxide as an additive. The manufacture of all pigmentary Titanium Dioxides inherently generates products with a range of particle sizes some of which will be in the nano range. However, the titanium dioxide additive use in the manufacture of these PEEK-CLASSIX™ grades contains less than 50 % of nanoparticles by number and should therefore not be considered as a nanomaterial according to the EU Commission Recommendation 2022/3689/EU. In addition, the titanium dioxide is encapsulated within the polymer matrix and classed as a solid mixture not in powder form.

This information is provided “as is”. It is not intended to amount to advice. Use of the product is at the customer’s/user’s risk. It is the customer’s/user’s responsibility to thoroughly test the product in each specific application to determine its performance, efficacy and safety for each end-use product, device or other application and compliance with applicable laws, regulations and standards. Mention of a product is no guarantee of availability. Victrex reserves the right to modify products, data sheets, specifications and packaging. **Victrex makes no warranties, express or implied (including, without limitation, any warranty of fitness for a particular purpose or of intellectual property non-infringement) and will not be liable for any loss or damage of any nature (however arising) in connection with customer’s/user’s use or reliance on this information, except for any liability which cannot be excluded or limited by law.** This document may be modified or retracted at any time without notice to the customer/user.

Victrex Manufacturing Limited (or another member of the Victrex group) is the owner or the licensee of all intellectual property rights in and to this document including the following trade marks, VICTREX, INVIBIO, JUVORA, APTIV, 450G, PEEK-OPTIMA, SHAPING FUTURE PERFORMANCE, LMPAEK, TRIANGLE (Device). All rights are protected by intellectual property rights including copyright under relevant national and international intellectual property laws and treaties. All rights reserved. Copyright © Victrex Manufacturing Limited 2024.



**Signed:** .....

Caroline Prisk  
Head of Regulatory Affairs and Product Stewardship

**Date:** 04-January-2024