COMPANY STATEMENT	**Medical Device Regulation (EU 2017/745)**
SUPPLIER	Invibio Ltd
PRODUCT NAME	**PEEK-OPTIMA™ Natural grades:** LT1, LT2, LT3 Granules, stockshapes and fine powder; **PEEK-OPTIMA™ Reinforced grades:** LT1CA30 Granules and Stock shapes; **PEEK-OPTIMA™ Ultra-Reinforced grades:** LT3CR stockshapes, LT3PPT unidirectional tape **PEEK-OPTIMA™ Image Contrast grades:** LT16BA, LT120BA, LT215BA, LT320BA Granules and Stock shapes **INVIBIO™ PEEK-OPTIMA™ HA Enhanced grades:** LT120HA Granules and Stock shapes **INVIBIO™ PEEK-OPTIMA™ Wear Performance grades:** MOTIS Granules and Stock shapes **PEEK-CLASSIX™ grades**: BC1, BC2, BC3, BC1-WH, BC2-WH, BC3-WH

This document is to confirm that the substances within the scope of the EU Medical Device Regulation (MDR) EU 2017/745, have not been intentionally added or used in the manufacturing processes of the Invibio products detailed above and to the best of our knowledge at this time, have not been intentionally added or used in the manufacturing processes of any included additives

Substances within the scope of the EU MDR (EU) 2017/745 are:

(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 (*Substances with harmonised classification and labelling up until the 18th Adaptation to Technical Progress, i.e. Commission Delegated Regulation (EU) No 2021/849 amending the CLP Regulation (EC) No 1272/2008*)

(b) Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified 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), in

accordance with the criteria relevant to human health among those laid down therein absence of >0.1% by weight.

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)*"
(*Candidate list of Substance of Very High Concern (SVHC) as published 17-January-2023*)

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.

Signed: .....

Caroline Prisk
Head of Regulatory Affairs and Product Stewardship

Date: 1-February-2023