

Document Creation date: 24th January 2024

COMPANY	Medical Davisa Demulation (Ell 2017/745)
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:
	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
	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:

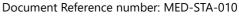
- (a) Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (Substances with harmonised classification and labelling up until the 20th Adaptation 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.

Invibio Ltd

Victrex Technology Centre, Hillhouse International, Thornton-Cleveleys, Lancashire, FY5 4QD, United Kingdom
Tel: +44 (0)1253 898 000 Fax: +44 (0)1253 898 001 Email: info@invibio.com
Registered in England and Wales No. 4088050 at address above
www.invibio.com







Revision number: 6

Document Creation date: 24th January 2024



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 23-January-2024)

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:

C. Purk

Caroline Prisk

Head of Regulatory Affairs and Product Stewardship

Invibio Ltd

Victrex Technology Centre, Hillhouse International, Thornton-Cleveleys, Lancashire, FY5 4QD, United Kingdom
Tel: +44 (0)1253 898 000 Fax: +44 (0)1253 898 001 Email: info@invibio.com
Registered in England and Wales No. 4088050 at address above
www.invibio.com



Date: 24-January-2024