

COMPANY STATEMENT	Materials of Biological Origin
SUPPLIER	Invibio Ltd
PRODUCT NAME	PEEK-OPTIMA™ Natural grades:
	LT1, LT2, LT3 Granules, stockshapes and fine powder;
	PEEK-OPTIMA [™] Reinforced grades:
	LT1CA30, LT1DA30 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
	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 <u>no</u> materials of biological origin* have been added or used in the manufacturing processes of the Invibio grades listed above.

*materials of biological origin are defined as materials incorporating derivatives of tissues or cells of human origin, animal origin or their derivatives which are non-viable or rendered non viable (as referred to in EU MDR2017/745 annex 1 section 13 and regulation EU 722/2012, protecting against the risk of transmitting animal spongiform encephalopathies e.g. BSE and TSE)

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Signed:

Date: 13-November-2023

Caroline Prisk Head of Regulatory Affairs and Product Stewardship

