

COMPANY STATEMENT	Materials of Biological Origin
SUPPLIER	Invibio Ltd
PRODUCT NAME	<p>INVIBIO™ PEEK-OPTIMA™ Natural grades: LT1, LT2, LT3 Granules, stockshapes and fine powder;</p> <p>INVIBIO™ PEEK-OPTIMA™ Reinforced grades: LT1CA30, LT1DA30 Granules and Stock shapes;</p> <p>INVIBIO™ PEEK-OPTIMA™ Ultra-Reinforced grades: LT3CR stockshapes, LT3PPT unidirectional tape</p> <p>INVIBIO™ PEEK-OPTIMA™ Image Contrast grades: LT16BA, LT120BA, LT215BA, LT320BA Granules and Stock shapes</p> <p>INVIBIO™ PEEK-OPTIMA™ HA Enhanced grades: LT120HA Granules and Stock shapes</p> <p>INVIBIO™ PEEK-OPTIMA™ Wear Performance grades: MOTIS Granules and Stock shapes</p> <p>PEEK-CLASSIX™ grades: BC1, BC2, BC3, BC1-WH, BC2-WH, BC3-WH</p>
<p>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.</p> <p>*materials of biological origin are defined as materials incorporating derivatives of tissues or cells of human 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)</p>	

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Signed:

Caroline Prisk
Head of Regulatory Affairs and Product Stewardship

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