Invibio Device Component Manufacturing	QMS Template Identifier: MED-SOP-053 Appendix 3	Invibio BIOMATERIAL SOLUTIONS
	QMS Template Revision: 1	
	Document Reference: *MED-STA-054*	
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INVIBIO Regulatory Overview

Scope

In response to high levels of information requested by our customers, this document is intended to provide a comprehensive and timely initial response of regulatory information covering all Invibio product grades.

Contents

1. Manufacturer Information

Company Name: **Invibio Limited**
Address: Hillhouse International, Thornton- Cleveleys, Lancashire, FY5 4QD, United Kingdom.
Phone Number: +44 (0) 1253 898 000
Fax Number: +44 (0) 1253 898001
Homepage: https://invibio.com/
E-mail address: RAPS@invibio.com

Regional Importer Addresses

Victrex global office addresses available via the link - Victrex Global Sites

2. Company overview

Invibio, part of the Victrex plc group of companies, is a global leader in providing high-performance biomaterial solutions to medical device manufacturers. The company provides PEEK based polymers and compounds for short and long term patient contact applications, advanced technical and regulatory support, and manufacturing of components for spine, trauma and orthopedic and dental medical segments for the development of long-term implantable medical devices.

3. Material Safety Data Sheets (MSDS)

All product specific MSDS's are available on the Invibio website https://invibio.com/en/resources/msds

4. Regulatory Statements

The Regulatory statements referenced below can be found at : https://invibio.com/en/resources
Please refer to the link above for more information on our company statements and grade specific information.

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Allergens Statement

The substances described in Annex II of Regulation (EU) No 1169/2011, known as substances or products causing allergies or intolerances have not been intentionally added or used in the manufacturing processes of the Invibio products detailed in the regulatory statement 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.

Materials of Biological Origin Statement

No materials of biological origin* have been added or used in manufacturing processes the Invibio products detailed in the regulatory statement.
*Materials of biological origin are defined as materials incorporating derivatives of tissues or cells of human or animal origin or their derivatives which are non-viable or rendered non-viable (as referred to in regulation EU 722/2012, protecting against the risk of transmitting animal spongiform encephalopathies e.g. BSE and TSE)

California Proposition 65 Statement

The substances listed in the CP65 list "Chemicals known to the State of California to cause Cancer or Reproductive Toxicity have not been intentionally added or used in the manufacturing processes of the Invibio products detailed in the regulatory statements 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.

Please note, there is an exception statement for CLASSIX-WH grades containing titanium dioxide. For product grade specific CP65 statements, please follow the link in the 'Regulatory Statements' section above.

CMRT - Conflict Minerals Reporting Template

The Conflict Minerals Reporting Template (CMRT) is a free, standardized reporting template developed by the Responsible Minerals Initiative (RMI) that facilitates the transfer of information through the supply chain regarding mineral country of origin and the smelters and refiners being utilized. The template also facilitates the identification of new smelters and refiners to potentially undergo an audit via the RMI's Responsible Minerals Assurance Process (RMAP).
Invibio has a completed CMRT available for customers. Please follow the link in the 'Regulatory Statements' section above.

EMRT - Extended Minerals Reporting Template

The Extended Minerals Reporting Template (EMRT) is a free, standardized reporting template developed by the Responsible Minerals Initiative to identify pinch points and collect due diligence information in the cobalt and mica supply chains. This is a template that was formally launched on October 20, 2021.
Invibio has a completed EMRT available for customers. Please follow the link in the 'Regulatory Statements' section above.

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Medical Device Regulation (EU) 2017-745 Material Disclosure Statement

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 in the regulatory statement 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.

Nanoparticles Statement

No 'Nanoparticles' or 'Nanomaterial' substances have been generated in the manufacturing process, nor intentionally added to the Invibio products detailed in the regulatory statement as defined within the EU Commission Recommendation 2022/3689/EU.

PFAS Statement

Per and Polyfluoroalkyl substances (PFAS) have not been intentionally added, used or generated as by-products in the manufacturing processes of the Invibio products detailed in the regulatory statement and to the best of our knowledge at this time, have not been intentionally added, used or generated as by-products in the manufacturing processes of any included additives.

POPS Statement

The substances listed in European Regulation (EU) 2019/1021, Annex I (Part-A), Annex III and Annex IV, have not been intentionally added or used in the manufacturing processes of the Invibio products detailed in the regulatory statement and to the best of our knowledge at this time, have not been intentionally added or used in the manufacturing processes of any additives.

REACH

Invibio Ltd polymer grades are exempt from EU REACH registration requirements. However, the monomers used in the polymer manufacture are in scope and have been registered in accordance with EU REACH - Regulation (EC) No 1907/2006

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS)

The Invibio products detailed in the regulatory statement do not contain the restricted substances listed in Annex II of Directive 2011/65/EC or GB/T 26572-2011 at concentration values above the maximum specified values by weight.

TSCA Persistent, Bioaccumulative, and Toxic (PBT)

The United States Environmental Protection Agency (EPA) issued five final rules on January, 6th 2021 to reduce exposures to certain chemicals that are persistent, bioaccumulative and toxic (PBT). We confirm that to our knowledge, the substances listed, have not been intentionally added or used in the manufacturing processes of the Invibio products detailed in the regulatory statement and have not been intentionally added or used in the manufacturing processes of any additives

5. Substance Statements

For substance specific queries (for example Latex, BPA) please see the Non Intentionally Added Substance (NIAS) Statement. The statement is available via the link in the 'Regulatory Statements' section above.

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