European Union Medical Device Regulation (MDR)

Compliance with PEEK-OPTIMA™ polymer implantable devices

MATERIAL SAFETY

Material composition and hazardous substances requirement
- Disclose all raw materials used to manufacture a device
- Each substance/material up to 0.1% (1000 ppm)
- All hazardous materials

Material considerations
- How do materials evolve through manufacturing processes and clinical use?
  - Do they remain stable?
  - Does their reactivity change?

Finished medical device considerations
- Expect more focus on testing for:
  - Shelf-life
  - Ageing

SUPPLY CHAIN TRACEABILITY

PEEK-OPTIMA polymers are manufactured
- Under the full control of Invibio Biomaterial Solutions™
- Within a secure, integrated supply chain
- From monomer to specifier
- Under ISO 13485:2016 certification

Monomer Manufacturing

Polymer Manufacturing

Downstream Manufacturing

Finished Components*

*These products are not cleared for implantation or distribution.

POST-MARKET SURVEILLANCE

Post-market clinical evidence – are you ready?
- Increased requirement for clinical evidence to demonstrate safety and performance of medical devices under MDR
- Poses significant cost burden and resource constraints to spine medical device manufacturers

Invibio will manage selected clinical studies for medical device manufacturers
- Opportunity to collect quality clinical data
- Objective to generate marketing collateral and clinical publications on PEEK-materials and technologies

CLINICAL EVALUATION REPORTS (CER)

PEEK-OPTIMA Technical Dossier
- 20 years - proven clinical history captured in a single evaluation
- ~9M devices implanted worldwide – large volume of data and many references available for use
- Focused on spine indications including:
  - Filters down to 44 relevant papers with 3,000 cases
  - To be updated annually

~9M PEEK-OPTIMA Devices Implanted Worldwide
20 Years of Clinical History

Invibio Biomaterial Solutions
For further information call us toll free at 866-INVIBIO or +44 (0)1253 898000 or please visit our website at:

Invibio.com

REFERENCES

1. (EU) 2017/745 Annex I, Chapter 2, Section 10.4.1 Design and manufacture of devices.

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