

Application for exemption from EU REACH/PFAS control for fluoropolymers (PTFE)

Subject: Application for permanent exemption of fluoropolymer (PTFE)

Based on: First, its non-toxicity and excellent biocompatibility, low friction coefficient, etc., has been widely used in the medical industry;

Second, it has become an irreplaceable key material in the field of implant/interventional medical devices;

Third, medical devices made of it have a broad market demand and its importance to life and health.

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Submission date: August 22 2023

Polytetrafluoroethylene (PTFE), with its excellent biocompatibility, ultra-low friction coefficient and excellent anti-adhesion properties, is widely used in the field of implantation, intervention, filtration and other medical devices. PTFE thin-walled lined tubes, heat shrink tubes, coatings, films, etc., are irreplaceable key materials in the field of implantation/interventional medical devices such as minimally invasive interventional catheter, braided catheter, balloon stent, guide wire catheter sheath and artificial prosthesis. Among them, American ZEUS, Teleflex, Microlumen and other companies monopolize the entire market.

Taking minimally invasive interventional catheter as an example, among the interventional pathway products, angiography catheter, guiding catheter, microcatheter and all kinds of interventional device pathway delivery systems all adopt multi-layer composite catheter technology. Most of the multi-layer catheters on the market are three-layer structures, the inner layer is polytetrafluoroethylene etched lining tube, the middle layer is metal material such as braided mesh or spring, and the outer layer is polymer material. The internal teflon superslide provides minimal friction for instrument delivery. The most used PTFE lining on the market is the product provided by ZEUS in the United States, which is used by most medical device manufacturers with rich applications and stable quality, in addition to ZEUS, Teleflex and Microlumen and other companies.

Taking minimally invasive interventional high-value consumable guide wire as an example, polytetrafluoroethylene heat shrink tube is one of the essential core raw materials in the production process of guide wire. As an indispensable instrument for minimally invasive interventional surgery, guide wire is also known as the "lifeline", and the existing PTFE heat shrink tube raw material market is completely occupied by American companies such as ZEUS and Teleflex. ZEUS has a market share of about 70%. Combined with the market demand for urinary intervention and respiratory intervention, and with the development of medical technology, as well as more

hospitals with minimally invasive intervention qualifications, the market prospect is broader.

Reference file□Polytetrafluoroethylene (PTFE): A resin material for possible use in dental prostheses and devices