珠海巽丰特种塑料有限公司
A member of Wittenburg Group
医疗和食品领域，您的TPE合作伙伴

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Xunfeng Product Stewardship Bulletin (PSB) for Cawiton TPE grades intended to be used for medical and/or pharmaceutical applications (May 2018)
巽丰应用于医疗和/或制药的Cawiton® TPE材料的产品管理工作公告（PSB）（2018年5月）

Cawiton TPE grades intended for medical and/or pharmaceutical applications comply with the relevant laws and regulations as required. Being synthetic and latex-free, these products have proven to be strong alternatives for PVC and can as such be used in medical device components, medical and pharma packaging, medical tubing, etc. In order to be fit for purpose, the materials have to meet stringent demands, including biocompatibility to the levels required for the specific use, compliance with legislative and regulatory requirements, including compliance with environmental regulations.
应用于医疗或制药领域的Cawiton® TPE材料符合相关法律法规的规定。这些产品都是人工合成，不含乳胶，并且经证明完全可以替代PVC。其可用于医疗器械组件、医疗和制药包装和医用导管等。为迎合此目标，材料必须符合严格的要求及特定用途所需的生物相容性水平，遵守立法和法规要求，遵守环境法规。

Raw materials 原材料

All raw materials used in compounding of Cawiton TPE series of medical and pharmaceutical packaging grades are controlled for compliance with EU and USA food contact regulations, as laid down in Commission Regulation (EC) No 1935/2004; Commission Regulation (EU) 2011/10 as amended;
Cawiton® TPE系列医疗和制药包装品级的化合物所用的原材料均符合欧盟和美国的食品接触规范，符合第1935/2004号欧委会条例及委员会条例（EU）2011/10修订案的内容。
Commission Regulation (EC) 2023/2006; US FDA CFR Code of Federal Regulations Title 21 (April 2017).
欧委会条例（EC）2023/2006; 美国FDA CFR联邦第21号法规（2017年4月）
To minimize any potential biocompatibility issues, the thermoplastic elastomer base resins used are selected from product series of which representative grades have passed USP Class VI tests, involving:
1. systemic toxicity to determine the irritant effect of toxic leachables present in extracts,
2. intracutaneous tests to assess the localised reaction of tissue to leachable substances, and
3. implantation tests to evaluate the reaction of living tissue to the plastic.
为最大程度地减少潜在的生物相容性问题，在选择用于热塑性弹性体的基础树脂时，所选的产品系列的代表品级都通过了美国药典（USP）VI级的认证，包括：
1. 全身毒性试验，从而判定提取物中有毒浸出物的刺激作用，
2. 皮内试验可评估组织对可浸出物质的局部反应
3. 植入试验可评估活性组织对塑料的反应。
The usage of thermoplastic elastomers in general and Styrene Block Copolymers (SBC's) in particular is not covered by the European Pharmacopeia (EP). In case of SBC's such as SEBS, the paraffinic oil used as an extender is a medicinal white oil, which is compliant with the USP, EP and other Pharmacopeia's.
通用的热塑性弹性体和特定的苯乙烯嵌段共聚物（SBC’s）在欧洲药典（EP）中无规定。在诸如SEBS的苯乙烯嵌段共聚物中，用作增量剂的石蜡基油是药用白油，这符合USP，EP和其他药典的规定。
Also polyolefins (PP, PE) used are predominantly medical grades that meet the compositional requirements of the European Pharmacopeia or have been tested for compliance with the EP, and/or have passed USP Class VI testing.
同时产品使用的聚烯烃（PP，PE）的主要医用级别符合欧洲药典的成分要求，或经测试符合EP的规定，且/或通过了USP VI级测试。

Cawiton material biocompatibility
Cawiton®材料的生物相容性

In addition to careful raw material selection measures, in order to increase the level of assurance for our customers, a variety of Cawiton MT900 series finished products - for medical packaging film, for medical tubing, for medical stoppers and other injection-moulding applications - has been tested for biocompatibility according to ISO 10993-5 (in vitro cytotoxicity); ISO10993-10 (irritation, sensitization) and USP Class VI by various well-known accredited external laboratories. Due to the overlap between some tests in USP and

ISO10993, passing USP Class VI requirements will increase the likelihood of passing specific ISO10993 parts.
除了谨慎的原材料选择措施，我们遵照ISO10993-5 （体外细胞毒性）、ISO10993-10 (刺激、致敏)和USP VI级的标准，在许多可信赖的知名外部实验室中测试了一系列Cawiton® MT900成品，以便增加客户的安全等级，这些成品主要用于医疗包装薄膜、医用导管、医药胶塞和其他注射模塑。由于USP和ISO10993中有一些重复的试验，通过USP VI级要求将提高通过特定 ISO10993要求的可能性。
However, it is to be noted that it is always the responsibility of the supplier of the finished product to perform relevant tests to ensure that the complete application (package, device, etc.) fulfils the compliance criteria that have been set up for the product.
然而，需注意的是，成品供应商应始终负责进行相关测试，以确保成品应用（包装，器械等）符合为产品设置的遵从性标准。

Manufacturing processes, Quality and Consistency
生产过程、质量和一致性

Cawiton TPE series of materials for medical applications are all produced under strict quality control and the Xunfeng Manufacturing Site is accredited to ISO 9001 and has implemented ISO 13485. Good Manufacturing Practices implemented include a thorough and documented line clean-down; using a closed manufacturing system from the material blending stage to the packaging stage; special precautions to avoid contamination issues; usage of special clean clothing, shoe covers, gloves and hairnets in the operations area. As formulation changes may have severe consequences for medical customers, based on contractual agreement Xunfeng may implement a ”No change” policy after recipe, line & process conditions fixation. Any enforced changes in supplier raw material composition and/or quality will be communicated to and discussed with our customers well in advance. Electronic data storage facilitates lot-to-lot traceability of raw materials and process conditions.
医疗应用Cawiton® TPE系列材料的生产均经过严格的质量控制，巽丰的生产场地符合ISO 9001标准并执行了ISO 13485标准。所实施的良好操作规范包括对生产线彻底清洁并记录；从原料配合阶段到包装阶段都使用封闭的生产系统；使用特殊预防措施，防止污染；在操作区域使用特殊清洁衣物、鞋套、手套和发网。由于改变配方可能会对医疗客户产生严重的后果，巽丰将在配方、生产和加工情况确定下来后，基于合同实施“不修改”政策。任何供应商原材料成分和/或质量的改变将提前与我们的客户交流讨论。电子数据存储有助于跟踪每个批次之间的原材料和加工情况。

Please note that Xunfeng will not supply any product for applications mentioned below:
请注意巽丰不会供应以下提到的产品或者应用：
Cawiton grades in general are not designed or manufactured for use in human body implants or in contact with internal body fluids and tissues. Xunfeng has not performed clinical testing of Cawiton grades for implantation and/or internal body fluid (tissue) contact, and makes no representation, promise, or warranty concerning the suitability of these materials for use in such applications. The decision to use our materials for a specific application is solely at the customer’s own responsibility and risk, i.e. the customer is to determine that the medical device (component) or pharmaceutical or in vitro diagnostic application is safe and technically suitable for the intended use and meets all applicable legal requirements. Please note that Class III applications (according to EU Directive 93/42/EEC as amended by 2007/47/EC) as defined below are considered as ‘’high risk’’ applications, for which major polymer manufacturers tend to have highly restrictive supply policies. Therefore, detailed discussions with our raw material suppliers and with you as a Xunfeng customer will be required before the decision can be taken to supply material under indemnification contract.
常用的 Cawiton®品级的设计和生产不适用于人体植入或接触内部体液和组织。巽丰没有对 Cawiton®品级进行植入和/或内部体液（组织）接触方面的临床试验。对用于这些应用的材料的适用性不做任何声明、承诺或保障。将我们的材料用于特定应用的决定都是客户自己的应承担的责任和风险，即客户应决定医疗设备（组件）或制药或体外诊断的应用是否安全且技术上适用，是否符合所有适用的法律要求。请注意以下定义的三类应用产品（根据经 2007/47/EC 修订的 EU 指令 93/42/EEC）被视为“高风险”应用产品，其主要的聚合

物生产商往往有严格受限的供应政策。因此，我们的原料供应商，作为巽丰的客户的您以及我们需要在赔偿合同下决定供应材料之前详细讨论。

''High Risk Applications'' "高风险应用"

1. Body implant applications where materials are intended to be used for permanent implantation (more than 30 days in the body or in contact with body fluids and tissues).
2. Medical devices (components of medical devices) categorized as risk class III according to EU Directive 93/42/EEC as amended by 2007/47/EC.
3. Critical components in any medical device that support or sustain human life.

1. 材料用于长期的身体植入（在体内超过 30 天或接触体液和组织）；
2. EU93/42/EEC 指令 2007/47/EC 修正案中归类为三类产品的医疗器械（组件或医疗器械）；
3. 医疗器械中用于支撑或延续人体生命的关键组件。

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