

此为证书 CN09/20404 译本

SGS

下述组织

## 吉力士热塑混合材料（苏州）有限公司

中国江苏省苏州工业园区胜港街 77 号

的管理体系已经过审核，并被证明符合下述要求

**ISO 13485:2016**

**EN ISO 13485:2016**

所涉及的活动范围覆盖

用于无源医疗器械和有源非植入医疗器械的医用级热塑性弹性体及医用级改性塑料材料的设计和制造

用于无源医疗器械和有源非植入医疗器械的医用级改性塑料材料的销售

该证书的有效有效期自 2024 年 10 月 09 日 至 2027 年 02 月 19 日 并须经过符合要求的监督审核保持有效

版本号 8. 初始注册日期 2009 年 02 月 19 日

在此范围内出具了多张证书，主证书编号为 CN09/20404

在其它场所实施的认证活动在后续页面上列出

*L. Moran*

签署

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此为证书 CN09/20404 译本, 续  
**吉力士热塑混合材料 (苏州) 有限公司**

**SGS**

**ISO 13485:2016**  
**EN ISO 13485:2016**

版本号 8

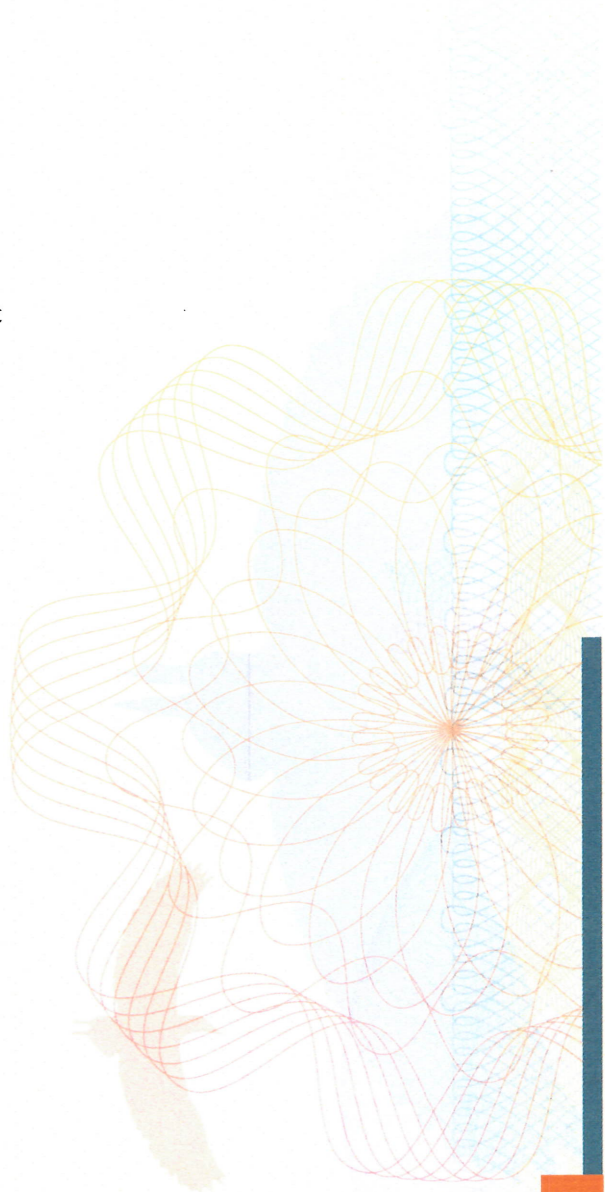
**场所**

吉力士热塑混合材料 (苏州) 有限公司  
中国江苏省苏州工业园区胜港街 77 号  
用于无源医疗器械和有源非植入医疗器械的医用级热塑性弹性体的设计和制造

普立万聚合体 (苏州) 有限公司  
中国江苏省苏州工业园区胜港街 77 号  
用于无源医疗器械和有源非植入医疗器械的医用级改性塑料材料的制造

埃万特有限公司  
中国江苏省苏州工业园区胜港街 77 号  
用于无源医疗器械和有源非植入医疗器械的医用级改性塑料材料的销售

普立万企业管理 (上海) 有限公司  
中国 (上海) 自由贸易试验区金苏路 200 号 20 幢 201 室  
用于无源医疗器械和有源非植入医疗器械的医用级改性塑料材料的设计



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Certificate CN09/20404

The management system of

# GLS Thermoplastic Alloys (Suzhou) Co., Ltd.

No. 77, Shenggang ST., Suzhou Industrial Park, Jiangsu Province, 215024, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Design and manufacture of medical grade thermoplastic elastomers and medical grade plastic compounding material for non-active medical devices and active medical devices (non-implantable)  
Sales of medical grade plastic compounding material for non-active medical devices and active medical devices (non-implantable)

This certificate is valid from 09 October 2024 until 19 February 2027 and remains valid subject to satisfactory surveillance audits.

Issue 8. Certified since 19 February 2009

Multiple certificates have been issued for this scope, the main certificate is numbered CN09/20404

Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

Liz Moran

Business Manager

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Certificate CN09/20404, continued

# GLS Thermoplastic Alloys (Suzhou) Co., Ltd.

**ISO 13485:2016**

**EN ISO 13485:2016**

Issue 8

## Sites

GLS Thermoplastic Alloys (Suzhou) Co., Ltd.

No. 77, Shenggang ST., Suzhou Industrial Park, Jiangsu Province, 215024, P.R. China

Design and manufacture of medical grade thermoplastic elastomers for non-active medical devices and active medical devices (non-implantable)

PolyOne-Suzhou, China

No. 77, Shenggang ST., Suzhou Industrial Park, Jiangsu Province, 215024, P.R. China

Manufacture of medical grade plastic compounding material for non-active medical devices and active medical devices (non-implantable)

Avient China Co., Ltd.

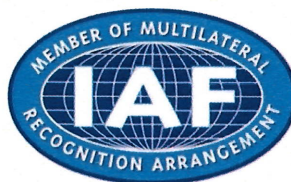
No. 77, Shenggang ST., Suzhou Industrial Park, Jiangsu Province, 215024, P.R. China

Sales of medical grade plastic compounding material for non-active medical devices and active medical devices (non-implantable)

PolyOne Management (Shanghai) Co., Ltd.

Room 201, Building 20, No. 200 JinSu Road, Shanghai Free Trade Zone, 200131, P.R. China

Design of medical grade plastic compounding material for non-active medical devices and active medical devices (non-implantable)



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