

# 吉力士热塑混合材料(苏州)有限公司 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

依据主证书 CN09/20404 中规定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改性塑料材料的制造

该证书的有效期自 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

此证书的有效性取决于主证书的有效性.

## L. Moran

签署

Liz Moran Business Manager

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#### Certificate CN09/20404.02



### GLS Thermoplastic Alloys (Suzhou) Co., Ltd. PolyOne-Suzhou, China

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

Has been assessed under the management system of the certified organisation defined in the main certificate CN09/20404 as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Manufacture 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 1

The validity of this certificate depends on the validity of the main certificate.

## L. Moran

Authorised by Liz Moran Business Manager

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