

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

质量管理体系 ISO 13485:2016

This is to certify that: Shanghai Eco Polymer Sci.&Tech.
Co., Ltd.
Room 301, No. 5, Lane 70, Haiji 6th Road
Lin-gang Special Area
(Shanghai) Pilot Free Trade Zone
201306, China

上海翊科聚合物科技有限公司
91310000MA1H32XY4N
中国
(上海) 自由贸易试验区
临港新片区
海基六路70弄5号301室
邮编: 201306

Holds Certificate No: **MD 827619**
持有证书

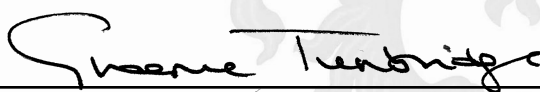
and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

并运行符合 ISO 13485:2016 要求的质量管理体系, 认证范围如下:

Design, manufacture and distribution of polymer material catheters for diagnostic equipment, reagent instruments, and interventional medical devices.

诊断仪器用、试剂仪器用、介入器械用高分子材料导管的设计、生产和销售。

For and on behalf of BSI:
BSI代表:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期: 2025-10-24

Effective Date 生效日期: 2025-10-24

Latest Revision Date 最新发证日期: 2025-10-24

Expiry Date 有效期至: 2028-10-23



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本证书信息亦可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。

The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

Information and Contact: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | 电话: +31 20 3460 780 BSI集团荷兰有限公司, 注册地荷兰, 注册号 33264284 | BSI集团控股有限公司成员

China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

Certificate No. **MD 827619**
持有证书:

Location 地点	Registered Activities 认证活动
Shanghai Eco Polymer Sci.&Tech. Co., Ltd. Room 301, No. 5, Lane 70, Haiji 6th Road Lin-gang Special Area (Shanghai) Pilot Free Trade Zone 201306, China 上海翊科聚合物科技有限公司 91310000MA1H32XY4N 中国 (上海) 自由贸易试验区 临港新片区 海基六路70弄5号301室 邮编: 201306	Design of polymer material catheters for diagnostic equipment, reagent instruments, and interventional medical devices. 诊断仪器用、试剂仪器用、介入器械用高分子材料导管的设计。
Shanghai Eco Polymer Sci.&Tech. Co., Ltd. Floor 1 and Floor 2 Unit Yi Building 24, No.528 Ruiqin Road Pudong New District Shanghai 201201, China 上海翊科聚合物科技有限公司 91310000MA1H32XY4N 中国 上海 浦东新区 瑞庆路528弄24幢乙号1层和2层 邮编: 201201	Manufacture and distribution of polymer material catheters for interventional medical devices. 介入器械用高分子材料导管的生产和销售。

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China Headquarters (Beijing): 2008 East Ocean Centre, 24A Jianguomenwai, Beijing, 10004, China, Tel: +86 10 85073000, A Member of the BSI Group of Company. 中国总部 (北京): 北京市
建国门外大街甲24号东海中心2008室 邮编: 100004 电话: +86 10 85073000 BSI集团公司成员。

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Location 地点	Registered Activities 认证活动
Xianju Eco New Material Sci.&Tech. Co., Ltd. Building 1 & Building 3 No.1 Dingshan Road Baita Industrial Cluster, Xianju Economic Development Zone Baita Town, Xianju County Taizhou City Zhejiang 317317, China 仙居翊科新材料科技有限公司 91331024MA2KBEKA6W 中国 浙江省 台州市仙居县白塔镇 仙居县经济开发区 白塔工业集聚区鼎山路1号 1号楼、3号楼 邮编: 317317	Manufacture of polymer material catheters for diagnostic equipment, reagent instruments, and interventional medical devices. 诊断仪器用、试剂仪器用、介入器械用高分子材料导管的生产。



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