

Located in the Sterigenics E-beam facility in Chuansha Economic Park, the SteriPro Laboratory offers extensive microbiological and analytical testing. Testing is performed by well-trained staff members under the direction of a qualified microbiologist and is fully compliant with ISO standards. Validation services are also offered to verify procedures.

In addition to test results, customers can count on SteriPro staff members to provide advice, insights and interpretations of tests results—all for the purpose of helping the manufacturer improve process performance and enhance speed to market.

If required tests are not included below, Shanghai staff members can quickly coordinate with SteriPro Laboratories in either Europe or the USA to deliver the needed services.

位于川沙经济园区的Sterigenics电子束技术厂内，SteriPro®实验室提供全面的微生物和分析检测。在一位合格的微生物学家的指导下，并完全按照ISO标准，由训练有素的工作人员进行检测。本公司也提供验证服务以核实灭菌过程。

除检测结果外，客户可以信任SteriPro工作人员为其检测结果提供建议、独到的见解和解释——目的是为了帮助制造商改进过程绩效并加快上市速度。

如以下不包含要求的检测项目，上海工作人员可以快速与美国或欧洲的SteriPro实验室协调，提供需要的服务。

Testing for E-beam Sterilisation Needs

Initial product bioburden: Used to determine the level and type of contamination on product before sterilisation. Tests are performed for:

- Aerobic bacteria
- Spore-forming bacteria
- Anaerobic bacteria
- Fungus/yeast and moulds

Product sterility testing: Used to demonstrate product sterility, and as part of dose audit/dose setting used to validate the sterilisation process.

Tests are performed for:

- Entire devices
- Sample portions

Bacterial endotoxin testing (LAL or limulus amebocyte lysate): Used to determine the level of endotoxins remaining on product after sterilisation.

Testing for Ethylene Oxide Processing Needs

Initial product bioburden: Used to establish the level and type of contamination on product before sterilisation. Tests are performed for:

- Aerobic bacteria
- Spore-forming bacteria
- Anaerobic bacteria
- Fungus/yeast and moulds

电子束灭菌需要的检测

初始产品生物负荷: 用以决定产品在灭菌前的污染度和类型。进行下列的检测:

- 好氧性细菌
- 芽孢形成菌
- 厌氧性细菌
- 真菌/酵母及霉菌

产品无菌检测: 用以展示产品无菌性, 并作为剂量审查/剂量设置的一部分用以验证灭菌过程。进行下列的检测:

- 整个器械
- 抽样部分

细菌内毒素检测 (LAL又称鲎试剂): 用以决定灭菌后残留于产品上的内毒素含量。

环氧乙烷处理需要的检测

初始产品生物负荷: 用以确定灭菌前产品上的污染度和类型。进行下列检测:

- 好氧性细菌
- 芽孢形成菌
- 厌氧性细菌
- 真菌/酵母及霉菌

Biological indicator (BI) culture and testing: Used for routine monitoring of the sterilisation cycle, and for the culture, test and counting of organisms remaining on BIs after a validation process. These tests are performed in the laboratory at the Sterigenics EO facility in Lingang.

Product sterility testing: Used to demonstrate that the resistance of the natural bioburden on product is less than that used on a biological indicator.

Residual testing on products post sterilisation: Used to determine both the type of residual, ethylene oxide, ethylene chlorohydrin or ethylene glycol and the amount. These tests can be done to create a “curve” to predict the aeration time required to ensure a “safe” product as defined in ISO 10993-7, or as a single-point check on products.

Bacterial endotoxin testing (LAL or limulus ameocyte lysate): Used to determine the level of endotoxins remaining on product after sterilisation.

Other Testing Capabilities

Sterigenics-trained microbiologists are also able to assist manufacturers in setting up and running clean-room monitoring to measure microbial contamination using settle and contact plates, and airborne particle levels.

生物指标（BI）培养和检测：用于灭菌周期的常规监控，以及验证过程后培养、检测和计算残留于生物指标上的微生物。这些检测在临港内Sterigenics环氧乙烷厂的实验室中进行。

产品无菌检测：用以演示产品自然生物负荷的抗性少于使用生物指标的产品的抗性。

灭菌后产品上的残留物检测：用以决定残留物的种类（环氧乙烷、氯乙醇或乙二醇）及其数量。这些检测可用来绘制一个曲线，以便预测符合ISO10993-7定义的“安全”产品所需的通风时间，或作为产品的单点检查。

细菌内毒素检测（LAL又称鲎试剂）：用以决定灭菌后产品上残留的内毒素含量。

其他检测能力

Sterigenics培训的微生物学家也能够帮助制造商设置及运行洁净间监控，使用平皿和接触皿测量微生物污染，以及尘埃粒子量。

**To learn more about our sterilisation and testing services
please contact us at one of the locations listed below:**

Sterigenics Shanghai Co., Ltd. Electron Beam Services

588 Chuan Tu Road □ Chuansha, Pudong □ Shanghai, 201202
Tel +86 21 58599555 □ Fax +86 21 58599312 □ info@sterigenics.com

Sterigenics Shanghai Ethylene Oxide Ltd.

Yang Hao Road, Shuang Hui Road □ Yangshan Free Port □ Shanghai
Tel +86 21 58599555 □ Fax +86 21 58599312 □ info@sterigenics.com

Sterigenics International, Inc. Europe/Mid East/Africa/Asia

Remylaan □ 4c box 4 □ 3018 Leuven □ Belgium
Tel +32 (0)16 525220 □ Fax +32 (0)16 525230 □ info@sterigenics.com

Sterigenics International, Inc.

2015 Spring Road □ Suite 650 □ Oak Brook, IL 60523 □ USA
Tel 800.472.4508 □ Fax 630.928.1701 □ info@sterigenics.com

Or visit us at www.sterigenics.com

**如欲进一步了解我们的灭菌和检测服务，
请通过下列任何一个服务地点与我们联系：**

上海辐新辐照技术有限公司 电子束工厂

浦东新区川沙镇川图路588号， 201202
电话： +86 21 58599555 □ 传真： +86 2158599312 □ info@sterigenics.com

Sterigenics上海环氧乙烷公司

中国上海洋山深水港区 □ 洋浩路， 双惠路
电话： +86 21 58599555 □ 传真： +86 2158599312 □ info@sterigenics.com

Sterigenics International, Inc. Europe/Mid East/Africa/Asia

Remylaan □ 4c box 4 □ 3018 Leuven □ Belgium
电话： +32 (0)16 525220 □ 传真： +32 (0)16 525230 □ info@sterigenics.com

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电话： 800.472.4508 □ 传真： 630.928.1701 □ info@sterigenics.com

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