

此为证书 CN17/21005 译本

下述组织

# 卡尔托利（苏州）材料科技有限公司

中国江苏省苏州市高新区联港路 571 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

用于无菌医疗器械的吸塑包装及相关配件的设计和制造，包括衬板，保护垫，封口膜，注塑组件  
无菌医疗器械包装封口过程确认的服务

该证书的有效期自 2023 年 09 月 14 日 至 2026 年 09 月 13 日 并须经过符合要求的监督审核保持有效  
版本号 3. 初始注册日期 2017 年 09 月 14 日

签署

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Certificate CN17/21005

The management system of

# Cartolux Technology (Suzhou) Co., Ltd.

No. 571, Liangang Road, Suzhou New District, Suzhou City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

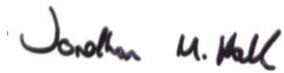
**EN ISO 13485:2016**

For the following activities

Design and Manufacture of Blister Packaging and Technical Parts including Mounting Cards, Protective Wedges,  
Lids and Injection Plastic Components Used for sterile medical device

Service for validation of sealing process for sterile medical device packaging

This certificate is valid from 14 September 2023 until 13 September 2026 and remains valid subject to satisfactory surveillance audits.  
Issue 3. Certified since 14 September 2017



Authorised by  
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