

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 Plastic Components Used for Non-active Medical Devices, Active Medical Devices (non-implantable), Active Implantable Medical Devices, In Vitro Diagnostic Medical Devices, Qualification of Packaging Process by Sealing for Medical Device Packaging.

This certificate is valid from 14 September 2020 until 13 September 2023 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 4 August 2023
Issue 2. Certified since 14 September 2017

Authorised by

SGS United Kingdom Ltd
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此为证书 CN17/21005 译本
This is an SGS translation of CN17/21005 Issue 2

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

用于无源医疗器械、有源非植入医疗器械、有源植入医疗器
械、体外诊断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,塑料组件;
医疗器械包装封口过程确认

该证书的有效期自 2020-09-14 至 2023-09-13
并须经过符合要求的监督审核保持有效
持续认证需在 2023-08-4 之前执行
版本号 2. 初始注册日期 2017-09-14

签署



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