



此为证书 CN15/30182 译本
This is an SGS translation of CN15/30182 Issue 5

下述组织

弓立 (厦门) 医疗用品 有限公司

中国福建省厦门市同安工业集中区同安园 139 号西侧 1-5 层



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

非无菌检查手套, 无菌和非无菌医用防护服, 无菌和非无菌医用口罩, 无菌和非无菌手术帽, 无菌和非无菌酒精棉片, 无菌和非无菌鞋套, 无菌和非无菌的手术衣, 无菌和非无菌无纺布块, 无菌手术手套, 无菌手术包, 非灭菌一次性隔离衣, 无菌和非无菌棉签, 无菌和非无菌纱布块, 无菌医用护理包, 无菌检查手套, 医用透气胶带, 无菌抽痰包的制造

该证书的有效期自 2019-07-09 至 2021-01-28
并须经过符合要求的监督审核保持有效
持续认证需在 2020-05-24 之前执行
版本号 5. 初始注册日期 2015-01-28

签署

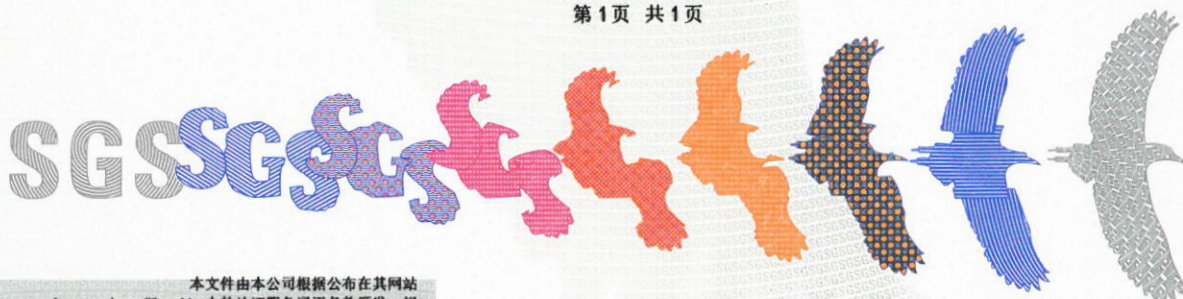


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HC SGS 13485 2016 0118

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Certificate CN15/30182

The management system of

SPRO Medical Products (Xiamen) Co., Ltd.

West of 1-5th Floor, No.139 Factory Bldg, Tong'an Garden, Tong'an Industry Area,
Xiamen City, Fujian Province, 361000, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Manufacture of non-sterile Examination glove,
sterile and non-sterile Coverall, sterile and non-sterile surgical face mask,
sterile and non-sterile Surgical cap, sterile and non-sterile Alcohol pad,
sterile and non-sterile Shoe cover, sterile and non-sterile Surgical gown,
sterile and non-sterile Non woven sponge, sterile Surgical glove,
Sterile Surgical kits, Non-sterile Disposable isolation gown,
Sterile and non-sterile Cotton tipped applicators,
Sterile and Non-sterile Gauze swab, Sterile nursing kit,
Sterile examination glove, Medical adhesive tape and Sterile suction kit**

This certificate is valid from 09 July 2019 until 28 January 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 24 May 2020

Issue 5. Certified since 28 January 2015

Authorised by

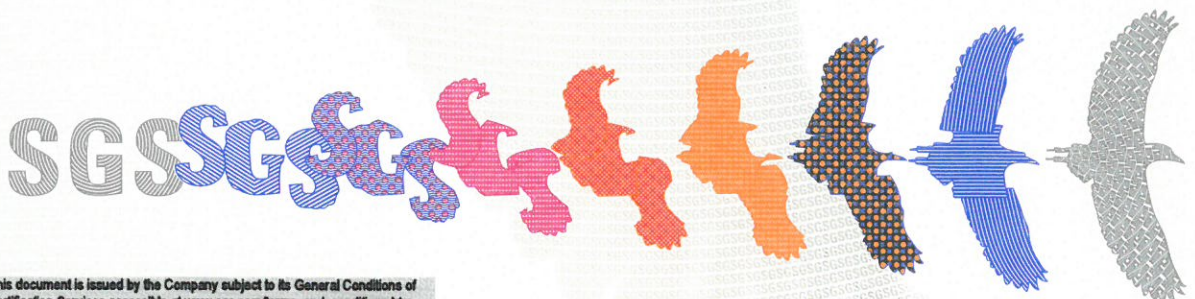
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