



Certificate CN09/31411

The management system of

GW Plastics (Dongguan) Ltd.

Building B10, Anli High Tech Park, Zhen' an Shangsha Road, Chang' an Town,
Dongguan City, Guangdong Province, 523870, 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 plastic injection moulded parts and assemblies used for
in-vitro diagnosis medical device, non-active medical device and active
medical device (non-implantable)**

This certificate is valid from 17 July 2018 until 16 July 2021 and remains
valid subject to satisfactory surveillance audits.
Re certification audit due before 23 June 2021
Issue 5. Certified since 16 July 2009

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1



0005



This document is issued by the Company subject to its General Conditions of
Certification Services accessible at www.sgs.com/terms_and_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional
issues established therein. The authenticity of this document may be verified at
<http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>.
Any unauthorized alteration, forgery or falsification of the content or appearance
of this document is unlawful and offenders may be prosecuted to the fullest
extent of the law.



此为证书 CN09/31411 译本
This is an SGS translation of CN09/31411 Issue 5

下述组织

东莞吉达优精密塑胶有限公司

中国广东省东莞市长安镇振安上沙路安力科技园 B10 栋



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

用于体外诊断医疗器械、无源医疗器械及有源非植入医疗器械的
注塑部品及其组件的制造

该证书的有效期自 2018-07-17 至 2021-07-16
并须经过符合要求的监督审核保持有效
持续认证需在 2021-06-23 之前执行
版本号 5, 初始注册日期 2009-07-16

签署



0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

第 1 页 共 1 页



本文件由本公司根据公布在其网站
www.sgs.com/terms_and_conditions.htm 中的认证服务通用条款颁发。提
请留意其中已确定的责任范围、商标和司法管辖事项。本文件的真
实性可在网站 <http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx> 中核实。任何未经授权的对
此文件的内容或外观的变更,伪造或篡改均属非法,违反者将会被依
法追究。