



# Certificate

No. Q8 001338 0003 Rev. 00

**Holder of Certificate:** **Freudenberg Medical Plastic & Metal Manufacturing (Shenzhen) Co. Ltd.**

101 of Block 2, F1-3 of Block 2  
F1 of Block 8 and F2 of Block 1  
Beiguang Industrial Park, Liangbai Road  
E Gong Ling Community, Pinghu Street  
Longgang District  
518111 Shenzhen City, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **The Provision of Production, Assembly and Distribution Services of Non-sterile Injection Molded Medical Components/Subassemblies**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8 001338 0003 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q8_001338_0003_Rev._00)

**Report No.:** GZ2313501

**Valid from:** 2023-08-31  
**Valid until:** 2026-08-30

**Date,** 2023-07-11



Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q8 001338 0003 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **Freudenberg Medical Plastic & Metal Manufacturing  
(Shenzhen) Co. Ltd.**

101 of Block 2, F1-3 of Block 2, F1 of Block 8 and F2 of Block 1,  
Beiguang Industrial Park, Liangbai Road, E Gong Ling Community,  
Pinghu Street, Longgang District, 518111 Shenzhen City,  
Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Production, Assembly and Distribution of Non-sterile Injection  
Molded Medical Components/Subassemblies

**APEC (ASIA) LIMITED**

5/F Manulife Place, 348 Kwun Tong Road, Kowloon, HONG  
KONG

Management of Non-sterile Injection Molded Medical  
Components/Subassemblies



# 认证证书

证书号. Q8 001338 0003 Rev. 00

证书持有者：

**科德宝医用塑胶五金制品（深圳）有限公司**

中华人民共和国广东省深圳市龙岗区平湖街道鹅公岭社区良白路  
倍光工业区2号101、2号厂房第1-3层、8号厂房第1层、1号厂房  
第2层 518111

认证标志：



认证范围：

**提供非灭菌的注塑医疗零部件/组件的  
生产、组装和分销服务**

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

TÜV 南德集团检测及认证规则所有适用要求也须得到遵守。详情及证书有效期请见

[www.tuvsud.com/ps-cert?q=cert:Q8 001338 0003 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q8_001338_0003_Rev_00)

报告号：

GZ2313501

生效期：

2023-08-31

有效期：

2026-08-30

Christoph Dicks

发证日期, 2023-07-11

Head of Certification/Notified Body

# 认证证书

证书号. Q8 001338 0003 Rev. 00

认证标准：

EN ISO 13485:2016  
医疗器械 - 质量管理体系 - 用于法规的要求  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

生产场地：

**科德宝医用塑胶五金制品（深圳）有限公司**

中华人民共和国广东省深圳市龙岗区平湖街道鹅公岭社区良白路  
倍光工业区2号101、2号厂房第1-3层、8号厂房第1层、1号厂房  
第2层 518111

生产、组装和分销：非灭菌的注塑医疗零部件/组件

**安柏斯（亚洲）有限公司**

香港九龙观塘道348号宏利广场5楼

管理：非灭菌的注塑医疗零部件/组件