



Product Service

CERTIFICATE

No. Q6 17 06 01338 001

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

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



Certification Mark:



Scope of Certificate: **Production, Assembly and Distribution 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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1713501

Valid from: 2017-08-31

Valid until: 2020-08-30

Date, 2017-08-03

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CERTIFICATE**No. Q6 17 06 01338 001****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.
F1-3 of Block 2 and F1 of Block 8, Beiguang Industrial Park,
Liangbai Road, E Gong Ling, Pinghu Town, Longgang District,
518111 Shenzhen City, Guangdong Province, PEOPLE'S
REPUBLIC OF CHINA

APEC (ASIA) LIMITED
LEVEL 54 HOPEWELL CENTRE, 183 QUEEN'S ROAD EAST,
WANCHAI, HONG KONG



Product Service

认证证书

证书号: Q6 17 06 01338 001

证书持有者:

科德宝医用塑胶五金制品(深圳)有限公司
中国广东省深圳市龙岗区平湖街道鹅公岭良白路
倍光工业园2号厂房第1-3层、8号厂房第1层
邮编: 518111

认证标志:



认证范围:

非灭菌的注塑医疗零部件/组件的生产、组装和销售

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上述所列标准要求的质量体系(删除第7.3条款)。

报告号: GZ1713501

生效期: 2017-08-31
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Product Service

认证证书

证书号: Q6 17 06 01338 001

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
 中国广东省深圳市龙岗区平湖街道鹅公岭良白路
 倍光工业园2号厂房第1-3层、8号厂房第1层
 邮编: 518111

安柏斯(亚洲)有限公司
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