



Certificate

No. Q5 104849 0001 Rev. 01

Holder of Certificate: **Triplex International Biosciences (China) Co., LTD.**

Unit 101, 201, and 301, No. 2041
Unit 101, 201, and 501, No. 2045, Xizhou Road
Tongan District
361100 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In-vitro Diagnostic Kit for Fertility Diagnosis, In-vitro Diagnostic Kit for Tumor marker, In-vitro Diagnostic Kit for Infectious Diseases, Nucleic Acid Extraction Reagent, Staining Solution and Supporting Instruments**

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). See also notes overleaf.

Report No.: GZ2041401

Valid from: 2020-06-30

Valid until: 2023-04-01

Date, 2020-06-30

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 104849 0001 Rev. 01

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):

Triplex International Biosciences (China) Co., LTD.
Unit 101, 201, and 301, No. 2041, Unit 101, 201, and 501, No. 2045,
Xizhou Road, Tongan District, 361100 Xiamen, PEOPLE'S
REPUBLIC OF CHINA



Product Service

认证证书

证书号. Q5 104849 0001 Rev. 01

证书持有者 :

泰普生物科学 (中国) 有限公司

中华人民共和国厦门市同安区西洲路2041号101、201、301单元 ;
2045号101、201、501单元 361100

认证标志 :



认证范围 :

设计和开发、生产和分销 :

生育诊断体外诊断试剂盒、肿瘤标示物体外诊断试剂盒、
传染病体外诊断试剂盒、核酸提取试剂、染色液及配套仪器

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。

报告号 :

GZ2041401

生效期 :

2020-06-30

有效期 :

2023-04-01

Christoph Dicks

发证日期, 2020-06-30

Head of Certification/Notified Body

认证证书

证书号. Q5 104849 0001 Rev. 01

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：

泰普生物科学 (中国) 有限公司

中华人民共和国厦门市同安区西洲路2041号101、201、301单元；

2045号101、201、501单元 361100