



证明书

CERTIFICATE



中国国际贸易促进委员会暨中国国际商会
China Council for the Promotion of International Trade is China Chamber of International Commerce

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中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE



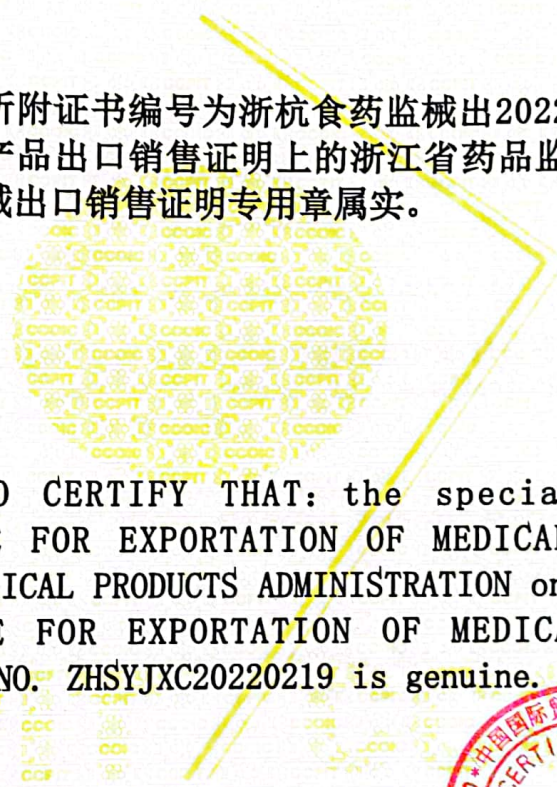
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号码 No.

兹证明：在所附证书编号为浙杭食药监械出20220219号医疗器械产品出口销售证明上的浙江省药品监督管理局医疗器械出口销售证明专用章属实。



THIS IS TO CERTIFY THAT: the special seal for CERTIFICATE FOR EXPORTATION OF MEDICAL DEVICE of ZHEJIANG MEDICAL PRODUCTS ADMINISTRATION on the annexed CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS CERTIFICATE NO. ZHSYJXC20220219 is genuine.



China Council for the Promotion of International Trade

授权签字:

Authorized Signature:

Chen Cheng

日期: 2022年11月09日
(Date: Nov. 09, 2022)

证明查询网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：浙杭食药监械出 20220219 号
Certificate NO.：浙杭食药监械出 20220219 号

产品名称：实时荧光定量 PCR 分析仪等产品，见附件（共 2 页）
Product(s)：QuantGene 9600 Fluorescent Quantitative Detection
System, etc. See Attachment (2 Pages)

规格型号：见附件（共 2 页）
Model: See Attachment (2 Pages)

产品注册或备案凭证号：见附件（共 2 页）
Registration certificate(s): See Attachment (2 Pages)

生产企业：杭州博日科技股份有限公司
Manufacturer: Hangzhou Bioer Technology Co., Ltd.

生产企业住所：浙江省杭州市高新技术产业开发区滨安路 1192 号
Address of manufacturer: 1192 BinAn Rd, Binjiang District 310053
Hangzhou PEOPLE'S REPUBLIC OF CHINA

生产许可或备案凭证号：浙食药监械生产许 20150033 号
Manufacturing License(s): 浙食药监械生产许 20150033 号

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制，出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted. The exporter should assure that exporting medical devices meeting requirements of the importing country(region).

证明有效日期至：2024 年 04 月 21 日
This certification valid until: 2024/04/21

备注：/
Remark: /

Zhejiang Medical Products Administration

(浙江省药品监督管理局)

2022 年 04 月 22 日

(出具单位盖章)



附件

ATTACHMENT

证书编号：浙杭食药监械出 20220219 号
Certificate NO.: 浙杭食药监械出 20220219 号



序号 SN	产品名称 Product(s)	规格型号 Model	产品注册证号 Registration certificate(s)
1	实时荧光定量 PCR 分析仪 QuantGene 9600 Fluorescent Quantitative Detection System	FQD-96C	国械注准 20213220056
2	实时荧光定量 PCR 分析仪 LineGene Mini Fluorescent Quantitative Detection System	FQD-16A	国械注准 20193220680
3	荧光定量聚合酶链 反应 (PCR) 检测 系统 LineGene 9600 PlusFluorescent Quantitative	FQD-48A; FQD-96A	国械注准 20153220273
4	巨细胞病毒 CMV 检测试剂盒 (荧光 定量 PCR 法) CMV Detection Kit(Fluorescence Quantitative PCR)	48 人份/盒 48T	国械注准 20143402002

附件


ATTACHMENT

证书编号：浙杭食药监械出 20220219 号
 Certificate NO.: 浙杭食药监械出 20220219 号



序号 SN	产品名称 Product(s)	规格型号 Model	注册证号 Registration certificate(s)
5	基因扩增仪 Thermal Cycler	模块不可互换型：TC-96/T/H (a)、 TC-96/G/H (b)、TC-24/H (b)、 TC-96/G/H (b) A、TC-96/G/H (b) B、 TC-96/G/H (b) C、TC-S/96/G/H (b) BA、TC-S/96/G/H (b) BB； 模块可互换型：TC-XP-A、TC-XP-B、 TC-XP-C、TC-XP-D、TC-XP-E、 TC-XP-G、TC-E-96G、TC-E-48D、 TC-EA-B-96GA、TC-EA-B-48DA、 TC-EA-B-3048UA、TC-EA-B-384GA、 TC-EA-B-41A	浙械注准 20172220742
6	微生物鉴定和药敏 分析仪 ATB Expression	ATB 1525 Expression	浙械注准 20142220042
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Tổng lãnh sự quán Việt Nam tại Thượng Hải
Consulate General of Vietnam in Shanghai

HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: Việt Nam
Country: Vietnam

Giấy tờ, tài liệu này
This public document

2. Do ông/bà: Tang Zhi Bao ký
Has been signed by: Tang Zhi Bao ký

3. Với chức danh: Trưởng phòng Hợp pháp hóa
Acting in the capacity of: Section Chief

4. Và con dấu của: Bộ Ngoại giao Trung Quốc
Bears the seal/stamp of: Ministry of Foreign Affairs of the People's Republic of China.


Được hợp pháp hóa lãnh sự
Certified

5. Tại: Thượng Hải
At: Shanghai

6. Ngày/on: 17/11/2022

7. Cơ quan cấp: TLSQ Việt Nam tại Thượng Hải
By: Consulate General of Vietnam in Shanghai.

8. Số/Nº: 365/TH/2/2022

Tổng lãnh sự/ Consul General

Nguyễn Thế Tùng

