PRODUCT NAME

产品名称

Fast real-time fluorescence PCR analyzer

实时荧光 PCR 分析仪

BTK-8

Version: 4.0

版本：4.0

2021/4/15

CE Certification- IVD Notification Certificate

CE 证书- IVD Notification 证书

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER — Obelis — SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: PMM 1131-2021

Order No.: OG 0814-2022

BELGIUM

Date: 12/04/2021

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: BIOTEKE CORPORATION (WUXI) CO., LTD

ADDRESS: 4TH FLOOR, D5. NO. 1719, HUISHAN AVENUE, WUXI CITY 214174 JIANGSU, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 30/03/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (2 PAGES, 1 DEVICE)

As of the 01/04/2021, and as long as the manufacture will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Brussels

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B–1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

CE Certification- IVD Notification Certificate
CE 证书- IVD Notification 证书

Order No. : OG 0814-2022
Ref No. : PMM 1131-2021

Annex A – List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	BTK-8	Fast real-time fluorescence PCR analyzer	Real-time fluorescence PCR analyzer	According to the operating parameters input by the computer, the temperature of the module component for placing the reagent sample is controlled to change, the reagent sample is subjected to high temperaturedenaturation, low temperature annealing (refolding), and the temperature extension process cycle is performed to amplify the reagent sample and pass. The photoelectric system detects	56706	other

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

CE Certification- IVD Notification Certificate
CE 证书- IVD Notification 证书

Obelis s.a.

Signature:

Stamp:

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

CE Certification-E.A.R. Certificate

CE 证书- E.A.R.证书

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

REF. NO. : PMM 1130-2021
ORDER NO. : OG 0814-2021

DATE: 12/04/2021

MANUFACTURER: BIOTEKE CORPORATION (WUXI) CO., LTD
4th Floor, D5. No. 1719, Huishan Avenue, Wuxi City
214174 Jiangsu, China

FACILITIES: BIOTEKE CORPORATIO(WUXI) CO., LTD
4th Floor, D5. No. 1719, Huishan Avenue, Wuxi City
214174 Jiangsu, China

PRODUCT CATEGORIES: Please See Annex A - List of Devices (1 Device, 2 Pages)

MODELS: Please See Annex A - List of Devices (1 Device, 2 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on September 1st, 2020.*

G. ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

*This is not a CE mark and is only provided as a template for informational purposes.

CE

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00453116 – 22/02/2019

CE Certification-E.A.R. Certificate
CE 证书- E.A.R.证书

Order No. : OG 0814-2021
Ref No. : PMM 1130-2021

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	BTK-8	Fast real-time fluorescence PCR analyzer	Real-time fluorescence PCR analyzer	According to the operating parameters input by the computer, the temperature of the module component for placing the reagent sample is controlled to change, the reagent sample is subjected to high temperaturedenaturation, low temperature annealing (refolding), and the temperature extension process cycle is performed to amplify the reagent sample and pass. The photoelectric system detects	56706	other

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

CE Certification-E.A.R. Certificate
CE 证书- E.A.R.证书

Obelis s.a.

Signature:

Stamp:

G.ELKAYAM
C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

CE Certification- Notify body: 2853

CE 证书- 欧盟公告机构：2853

CERTIFICATE | CERTIFICADO | ZERTIFIKAT | CERTIFICATO | 証書 | 证书 | 證書 | 증명서 | شهادة

CERTIFICATE

Certificate No: BG/TC/0009/25.03.2021

Applicant: Name, address	BioTeke Corporation（Wuxi）Co., Ltd. 4th Floor, D5&2nd Floor, D3&1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi,Jiangsu CN 214174
Manufacturer: Name, address	BioTeke Corporation（Wuxi）Co., Ltd. 4th Floor, D5&2nd Floor, D3&1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi,Jiangsu CN 214174
Product:	Fast real-time fluorescence PCR analyzer
Type / Models:	BTK-8
Related Directives and Annex	2014/35/EU 2014/30/EU
Related Standards	EN 61010-1:2010+A1:2019, EN 61326-1:2013
Technical file Comments:	TCF-03-2020476-LVD, TCF-03-2020476-EMC

This certificate is provided to the applicant on the basis of the information provided by the manufacturer or the applicant, and it gives to the applicant the right to use and affix the ECTI CERT Mark on their products accordingly to the ECTI CERT regulation for voluntary certification about its release and its use. The latest revision of the Regulation is available and can be downloaded from the website www.ecti-bg.com. Therefore, it does not imply any assessment on the safety and compliance of the product, or the production process of this product by ECTI CERT.

CE

25.03.2021
Date of Issue

KRASIMIR MIHAYLOV GREBENAROV
Digitally signed by KRASIMIR MIHAYLOV GREBENAROV
Date: 2021.03.26 10:12:45 +02'00'
Manager

CE marking is only used on the product if all the relative EU Directives or Regulations are complied with. EC Declaration of Conformity and the technical documents are prepared by the manufacturer or its applicant who puts the product on the market.

The validity of this certificate (4 years from the date of issue) can be checked on the ECTI CERT Homepage.

ECTI CERT Ltd.
Bulgaria, Sofia, 133 Tsarigradsko Shosse Blvd., Office 729
www.ecti-bg.com
Tel.: +359 878 87 75 77
E-mail: info@ecti-bg.com

FDA Registration
FDA 注册

(./help/index.html)

DRLM Home (mainMenu.htm) View Your Registrations and Listings

Registration Information

Facility

Registration Number	3016837106
FEI Number	3016837106
Registration Status	Active
Registration Status Reason	Registration changed from inactive to active
Initial Importer	N
Facility Name	BIOTEKE CORPORATION (WUXI) CO., LTD
Facility Address	4TH FLOOR, D5, NO.1719,HUISHAN AVENUE , WUXI , JIANGSU , 214174 , CHINA

Owner/Operator

Owner/Operator Number	10071745
Contact Name	ZHITU ZHOU
Business Name	BIOTEKE CORPORATION (WUXI) CO., LTD
Address	4TH FLOOR, D5, NO.1719,HUISHAN AVENUE WUXI , JIANGSU , 214174 , CHINA
Phone Number	86 - 510 - 8866 - 1198
Fax Number	
E-mail	biotekeinfo@163.com

Official Correspondent

Contact Name	ZHITU ZHOU
Business Name	BIOTEKE CORPORATION (WUXI) CO., LTD
Address	4TH FLOOR, D5, NO.1719,HUISHAN AVENUE WUXI , JIANGSU , 214174 , CHINA
Phone Number	86 - 510 - 8866 - 1198
Fax Number	
E-mail	biotekeinfo@163.com

U.S.Agent

Contact First Name	LEE
Contact Last Name	JO
Title	MR
Business Name	-
Full Address	1064 Doverfield Ave.,Hacienda Hts, California,91745 UNITED STATES
E-mail	Biotekeinfo@163.com
Phone Number	626-2883966
Fax Number	-

Registration Status

Expiration Date	2021-12-31
PIN - PCN	50304302 - 21458860

Previous (drlm.htm?_flowExecutionKey=_c1AF5B7EE-9049-B94D-F6F4-C5B063D7188C_kF38D65A8-FC99-6C3C-1E8A-ACD0E4B7E84A5_eventId=

FDA Registration
FDA 注册

Listing Number	Listing Status	Premarket Submission Number	Product Code(s)	Device Name	Action
D437518	Active	Enforcement	QMC	Transport medium, notified per the VTM guidance	
D434754	Active		JJC	ANALYZER, CHEMISTRY (SEQUENTIAL MULTIPLE, CONTINUOUS FLOW) CLINICAL USE	
D419420	Inactive		OOI	real time Nucleic acid amplification system	
D415901	Active		PPM	General purpose reagent	
D415360	Active	Enforcement	JSM	CULTURE MEDIA, NON-PROPAGATING TRANSPORT	
D412498	Active		FMH	CONTAINER, SPECIMEN, STERILE	
D404946	Active		KXG	APPLICATOR, ABSORBENT TIPPED, STERILE	
D402052	Active		JJH	CLINICAL SAMPLE CONCENTRATOR	
D396234	Active		NNI	CONTAINER, SPECIMEN, NON-STERILE	

FDA FURLS **DRLM**
Device Registration & Listing Module

DRLM Home > View Your Registrations and Listings

View Proprietary Names and Labeling

Listing Number D434754

Proprietary Name	Confidential	Device labeled for use	Device Identifier	Label
real-time fluorescent quantitative PCR instrument	N	other		
Fast real-time fluorescence PCR analyzer	N	other		

Close and Return

Product Code: JJC
Listing No.: D434754

Peru Registration exempt
秘鲁注册豁免型

Classification	IVD Medical device	
Does the product have temperature specification requirements?	☐Yes	☒No
Main Applicable Documentation Required by DIGEMID[3]	☐Biocompatibility Tests	☐Design and Verification Reports
	☐Risk Management	☐Sterilization Information
	☐Clinical Evaluation	☐Certificate of Conformance
	☐Manufacturing Process	☐Labels
Observations	In Peru IVD instruments are currently exempt of registration.	

If there is any accessory other than the ones listed in this chart, the accessory must be classified before its inclusion in the submission. Accessories can generally be included in the submission, if they are mentioned in the Free Sales Certificate or clearly marked in product IFUs or Brochures.
Internal Ref: IVD-H
Dicsy/Nanna

Instrument Test Report
仪器检测报告

江苏省电子信息产品质量监督检验研究院（江苏省信息安全测评中心）

检 测 报 告

委托单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
制造单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
生产单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
样品名称	快速实时荧光 PCR 仪			产品商标	FastQuant
型号规格	BTK-8				
样品数量	1	生产日期/批号	/	收样日期	2021.2.10
来样方式	☑委托方送样				
	☐抽样	抽样地点	/	抽样基数	/
检测日期	2021 年 2 月 24 日				
检测依据	1. GB/T 18268.1-2010 测量、控制和实验室用的电设备 电磁兼容性要求 第 1 部分：通用要求 2. GB/T 18268.26-2010 测量、控制和实验室用的电设备 电磁兼容性要求 第 26 部分：特殊要求 体外诊断（IVD）医疗设备				
检测结论	所送样品经检测所检项目符合检测依据栏所列标准要求。				
编制		审核		检验检测专用章	
批准	秦峰	签名：		（盖章）	
	批准日期： 2021 年 3 月 22 日				
备注					

检验检测专用章

Instrument Test Report
仪器检测报告

Jiangsu Electronic Information Product Quality Supervision & Inspection Institute
(Jiangsu Information Security Evaluation Center)

TEST REPORT

General information:	
Applicant. ..... :	BioTeke Corporation (Wuxi) Co., Ltd
Address ..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174
Manufacturer..... .....:	BioTeke Corporation (Wuxi) Co., Ltd
Address ..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174
Factory ..... :	BioTeke Corporation (Wuxi) Co., Ltd
Address ..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, CN 214174
Name of the sample..... :	Fast real-time fluorescence PCR analyzer
Trade Mark ..... :	FastQuant
Model/Type ..... :	BTK-8
Sample Quantity ..... :	1
Production Date / Lot No..... :	/
Date of receipt..... :	Feb. 10, 2021
Sample acquisition mode:	
☑ Client delivering sample ☐ Sampling Sampling Location..... : Sampling Base..... :	 / /
Date of test..... :	Feb. 24, 2021
Test Result ..... :	PASS
Tested by..... :	Cheng Zhaoping
Checked by ..... :	Meng Fanjun
Approved by(Name+ Signature):	Qin Feng
Date of issue:..... :	2021-03-22
Note	

Instrument Test Report
仪器检测报告

General sample information:

Composition and state of sample….: The power supply voltage of the EUT is 220VAC50Hz.

Sample Photograph(s)……..: See photos page

Main function description……..: /

Test Standard:

IEC60601-1-2:2004: Medical Electrical Equipment-Part 1-2:General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances requirements and tests

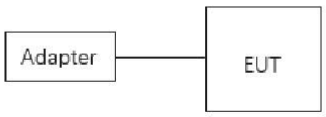
Test Instructions:

Received 1 set sample for testing, actual test 1 set. Please find corresponding test group and sample number in the test result. If the EUT is working normally, it means: the EUT's display is always on and the displayed data is normal.

Testing location/ address …..……..: /

Additional Information……..……..: /

EUT connection schematic diagram:



Possible test case verdicts:

- test case does not apply to the test object….:	N/A
- test object does meet the requirement……..:	P (Pass)
- test object does not meet the requirement…:	F (Fail)

Instrument Test Report
仪器检测报告

江苏省电子信息产品质量监督检验研究院（江苏省信息安全测评中心）

检 测 报 告

委托单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
制造单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
生产单位/地址	无锡百泰克生物技术有限公司/江苏省无锡市惠山区惠山大道 1719-5 号四层 A 区，1719-3 号 B 区二层，1719-16 号一层二层				
样品名称	快速实时荧光 PCR 仪		产品商标	/	
型号规格	BTK-8				
样品数量	1	生产日期/批号	/	收样日期	2021 年 2 月 10 日
来样方式	☑委托方送样				
	☐抽样	抽样地点	/	抽样基数	/
检测日期	2021 年 2 月 10 日至 2021 年 3 月 8 日				
检测依据	1. GB/T 14710-2009 《医用电器环境要求及试验方法》 2. GB 4793.1-2007 《测量、控制和实验室用电气设备的安全要求 第 1 部分：通用要求》 3. GB 4793.6-2008 《测量、控制和实验室用电气设备的安全要求 第 6 部分：第 6 部分：实验室用材料加热设备的特殊要求》 4. GB 4793.9-2013 《测量、控制和实验室用电气设备的安全要求 第 9 部分：实验室用分析和其他目的自动和半自动设备的特殊要求》 5.YY0648-2008《测量、控制和实验室用电气设备的安全要求 第 2-101 部分：体外诊断(IVD)医用设备的专用要求》				
检测结论	所送样品经检测，所检项目符合检测依据栏所列标准要求。				
编制	李晶晶	审核	冯建军	检验检测专用章	
批准	秦峰	签名：	秦峰	（盖章）	
	批准日期： 2021 年 3 月 10 日			检验检测专用章	
备注					

Instrument Test Report
仪器检测报告

TEST REPORT		
General information:		
Applicant. ..... :	BioTeke Corporation (Wuxi) Co., LTD.	
Address..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi City, Jiangsu Province, People Republic of China	
Manufacturer..... .....:	BioTeke Corporation (Wuxi) Co., LTD.	
Address..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi City, Jiangsu Province, People Republic of China	
Factory ..... :	BioTeke Corporation (Wuxi) Co., LTD.	
Address..... :	4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi City, Jiangsu Province, People Republic of China	
Name of the sample..... :	Fast real-time fluorescence PCR analyzer	
Trade Mark ..... :	/	
Model/Type..... :	BTK-8	
Sample Quantity ..... :	1	
Production Date / Lot No..... :	/	
Date of receipt..... :	2021.2.10	
Sample acquisition mode:		
☒ **Client delivering sample** ☐ **Sampling** **Sampling Location**.....: **Sampling Base** ..... :		
Date of test..... :	2021.2.10 ~ 2021.3.8	
Test Result ..... :	PASS	
Tested by..... :	Li Jingjing	检验检测专用章
Checked by ..... :	ShanDongbo	
Approved by(Name+ Signature):	Qin Feng	Qin Feng
Date of issue:..... :	2021-03-17	

QCR69-2-2006

Instrument Test Report
仪器检测报告

Jiangsu Electronic Information Product Quality Supervision & Inspection Institute
(Jiangsu Information Security Evaluation Center)

Note

General sample information:
Composition and state of sample….: Fast real-time fluorescence PCR analyzer
Sample Photograph(s)…….: See photo page
Main function description……..: /
Additional Information……..: /
Test Standard:
IEC 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements
Test Instructions:
Received 1 set sample for testing, actual test 1 set. Please find corresponding test group and sample number in the test result. Testing location/ address …..…..…..: No.100 Jinshui Road, WuXi, Jiangsu, P.R.China Additional Information……..…..…..:/
Possible test case verdicts:
- test case does not apply to the test object….: N/A - test object does meet the requirement……..: P (Pass) - test object does not meet the requirement…: F (Fail)

ISO 13485 Certificate
ISO 13485 证书

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2160603-1
Organization:	BIOTEKE CORPORATION (WUXI) CO., LTD. 4th Floor, D5, No.1719, Huishan Avenue, Wuxi City 214174 Jiangsu P.R. China
Scope:	Manufacture and Distribution of Nucleic Acid Extraction Devices, Nucleic Acid Extraction Reagents, Disposable Sampling Swab Kits

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	15096233 004
Effective date:	2021-02-03
Expiry date:	2024-02-02
Issue date:	2021-02-03

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

ISO 13485 Certificate
ISO 13485 证书

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2160603-1

Organization: BIOTEKE CORPORATION (WUXI) CO., LTD.
4th Floor, D5,
No.1719, Huishan Avenue,
Wuxi City
214174 Jiangsu
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	BIOTEKE CORPORATION (WUXI) CO., LTD. 4th Floor, D5, No.1719, Huishan Avenue, Wuxi City 214174 Jiangsu P.R. China	Distribution and service of Nucleic Acid Extraction Devices, Nucleic Acid Extraction Reagents, Disposable Sampling Swab Kits
/02	BIOTEKE CORPORATION (WUXI) CO., LTD. 2nd Floor, D3, No.1719, Huishan Avenue, Wuxi City, 214174 Jiangsu P.R. China	Manufacture of Nucleic Acid Extraction Reagents
/03	BIOTEKE CORPORATION (WUXI) CO., LTD. 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi City, 214174 Jiangsu P.R. China	Manufacture of Nucleic Acid Extraction Devices and Disposable Sampling Swab Kits

Report No.: 15096233 004

Effective date: 2021-02-03

Expiry date: 2024-02-02

Issue date: 2021-02-03

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

ISO 9001 Certificate
ISO 9001 证书

NOA

QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to Certify that the QUALITY MANAGEMENT SYSTEM of

BIOTEKE CORPORATION（WUXI）CO.,LTD

Registered Address:1st Floor, 2nd Floor, No. 1719-16, 2nd Floor, Area B, No. 1719-3, Area A, 4th Floor, No. 1719-5, Huishan Avenue, Huishan Economic Development Zone, Wuxi

has been assessed by NOA Certification
and found to comply with

GB/T 19001-2016 idt ISO9001:2015

Audit Address:4th Floor, Zone A, D5, Zone D, Life Park, No. 1719-5, Huishan Avenue, Huishan Economic Development Zone, Wuxi
For the scope of:Production and sales of first-class medical devices within the scope of qualification
Audit Address:The first floor and the second floor of No. 1719-16, The second floor of Zone B, No. 1719-3 Huishan Avenue, Huishan Economic Development Zone, Wuxi
Sub-scope:Production activities

Certificate Number: NOA20110840
Unified Social Credit Code: 913202065617502076
Certificate Issue Date: 14 Dec. 2020
Certificate Valid Until: 14 Dec. 2021

Certification Manager

NOA ISO 9001 MANAGEMENT CERTIFICATION

ANAB ACCREDITED MANAGEMENT SYSTEMS CERTIFICATION BODY

IAF

Date of Initial Certification: 14 Dec. 2020 Expire Date of Certification: 14 Dec. 2023

This certificate is issued by NOA testing & certification, the certificate holder shall accept surveillance audit by NOA and the certificate shall be renewed by NOA prior to its expiry date as required. To verify the validity of certificate, please visit www.noagroup.org . The certificate information is also available on the CNCA official website: www.cnca.gov.cn .

NOA Certification Service

Add.:Building 26,Lane 2777,East Jinxiu Road,Free Trade Zone,Shanghai,China Email:noa@noagroup.org

ISO 45001 Certificate
职业健康安全管理体系认证证书

CERTIFICATE

特此授予：

无锡百泰克生物技术有限公司
统一社会信用代码：91320206561750207 6

无锡惠山经济开发区惠山大道1719-5号四层A区、1719-3号B区二层、1719-16号一层二层

职业健康安全管理体系符合
GB/T 45001-2020/ISO 45001:2018

认证范围
一次性病毒采样管、核酸提取仪的生产相关的职业健康安全管理活动

证书编号：ARES/CN/I2101044S
证书签发日期：2021年02月07日　证书有效日期：2024年02月06日

每次监督审核时间与上次现场审核时间间隔不得超过12个月，且必须取得ARES签发的监督审核通过证明以确保证书有效性。

IAS ACCREDITED Management Systems Certification Body ACC NO. MSCB - 171

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

批准：

ARES International Certification Co., Ltd.
No.12-2, Ln. 187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan
TEL / 06-295 9696 (Rep. Line) FAX / 06-295 9667 www.ares-registration.com
本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）及 www.ares-china.cn 上查询

ISO 45001 Certificate
职业健康安全管理体系认证证书

CERTIFICATE

The Governing Board of
ARES International Certification Co., Ltd.
Hereby Grants To:

BIOTEKE CORPORATION (WUXI) CO., LTD.
Organization Credit Code: 913202065617502076

4th Floor, D5&2nd Floor, D3& 1st and 2nd Floor,D16, No.1719, Huishan Avenue, Wuxi

Has been assessed and found to be in accordance with the requirements of standard detailed below
GB/T 45001-2020/ISO 45001:2018

Scope
Manufacture of disposable virus sampling swab and nucleic acid extraction Management of Related Occupational Health and Safety Aspects.

Certificate No.: ARES/CN/I2101044S
Certificate Issue Date: 2021-02-07 Registration Expiration Date: 2024-02-06

The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, and the organization must obtain "surveillance audit approval notification" issued by ARES to ensure the validity of the certificate.

IAS ACCREDITED Management Systems Certification Body ACC NO. MSCB - 171

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Authorized by :

ARES International Certification Co., Ltd.
No.12-2, Ln. 187, Wenping Rd., Anping Dist., Tainan City 708, Taiwan
TEL / 06-295 9696 (Rep. Line) FAX / 06-295 9667 www.ares-registration.com
Check the validity of this certificate on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or www.ares-china.cn.

ISO 14001 Certificate
环境管理体系认证证书

环境管理体系认证证书

证书编号：GXZT002-21E10015R0S

兹证明：

无锡百泰克生物技术有限公司

统一社会信用代码/组织机构代码：91320206561750207 6

环境管理体系符合：

GB/T24001-2016/ISO14001:2015 标准

证书覆盖范围：一次性病毒采样管、核酸提取仪的生产及相关管理活动

注册地址：无锡惠山经济开发区惠山大道 1719-5 号四层 A 区、1719-3 号 B 区二层、1719-16

审核地址：无锡惠山经济开发区惠山大道 1719-5 号四层 A 区、1719-3 号 B 区二层、1719-16

颁证日期：2021年01月14日

有效期至：2024年01月13日

证书签发人

国信正通(北京)检验认证有限公司 证书专用章

此认证证书的有效性以左下角二维码扫描结果为准。

同时可登录认证机构网站:www.isogx.cn查询。

本证书信息可在国家认证认可监督管理委员会官方网站www.cnca.gov.cn 查询。

国信正通(北京)检验认证有限公司

中国·北京·昌平区天通中苑二区42号楼508室(102218)

ISO 14001 Certificate
环境管理体系认证证书

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: GXZT002-21E10015R0S

We hereby certify that the organization:

Bioteke (wuxi) Corporation Co., Ltd

Unified social credit code/Organization code: 913202065617502076

is in conformity with Environmental Management System Standard:

GB/T24001-2016/ISO14001:2015

The certificate is valid to the following product(s)/service:

the manufacture of disposable virus sampling swab kits and nucleic acid extraction system and related management action

Registration Address: 4th floor, D5, 3rd floor, D3, 1st &2 nd floor, D16, No.1719, Huishan Avenue, Wuxi

Audit Address: 4th floor, D5, 3rd floor, D3, 1st &2 nd floor, D16, No.1719, Huishan Avenue, Wuxi

Date of Issue : 14-01-2021

Date of Expiry: 13-01-2024

Certificates Appropriation

The Effectiveness of the Certificate is Subject to QR Code in the Left.
Meanwhile, You Can Search the CNCA Website:www.cnca.gov.cn
or Website of Certification Body www.isogx.cn

Guo Xin Zheng Tong (Beijing) Inspection & Certification Co.,Ltd.

Room 508, Building 42, Zone 2, Tiantongyuan, Changping District, Beijing, China (102218)

IPMS Certificate
知识产权管理体系认证证书

知识产权管理体系认证证书

【证书编号】ZJLH20IP0299R0M

兹证明

无锡百泰克生物技术有限公司

统一社会信用代码：91320206561750207 6

注册地址：无锡惠山经济开发区惠山大道1719-5号四层A区、1719-3号B区二层、1719-16号一层二层，邮编：214174

经营地址：无锡惠山经济开发区惠山大道1719-5号四层A区、1719-3号B区二层、1719-16号一层二层，邮编：214174

知识产权管理体系符合标准：GB/T 29490-2013

认证范围：荧光定量PCR仪的研发；核酸提取设备及其试剂、一次性使用病毒采样管、实验室消毒设备研发、生产、销售及所涉及采购活动的知识产权管理（资质许可范围内）。

注：认证注册范围不包括未获得有效的国家规定的相关行政许可、资质许可的产品、服务范围。

首次发证日期：2020 年 12 月 01 日

本次发证日期：2020 年 12 月 01 日

证书有效日期：2023 年 11 月 30 日

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。

本证书的有效性通过年度监督保持，在一个监督周期后，本证书必须与本机构颁发的监督审核合格通知书合并使用方可有效。查询证书有效状态请登录本机构网站 www.zjlhbjrz.com 或国家认监委网站 www.cnca.gov.cn，也可通过扫描二维码查询。

IPMS 中际连横认证

签发：

中际连横（北京）认证有限公司

地址：北京市朝阳区惠新南里6号3层1-3号309室 邮编：100029

IPMS Certificate
知识产权管理体系认证证书

Intellectual Property Management System (IPMS) Certificate

【RegistrationNumber：ZJLH20IP0299R0M】

This is to certify that the organization

BIOTEKE CORPORATION (WUXI) CO., LTD

Registered Address:4th Floor, D5& 2nd Floor, D3 & 1st and 2nd Floor D16,No.1719, Huishan Avenue, Wuxi City,214174 Jiangsu, China

OperationAddress:4th Floor, D5& 2nd Floor, D3 & 1st and 2nd Floor D16,No.1719, Huishan Avenue, Wuxi City,214174 Jiangsu, China.

Forthefollowingactivities meets the Chinese National StandardGB/T 29490-2013

Authentication Scope:

Intellectual property management in the development of a fluorescence quantitative PCR instrument; also in the research and development, production and sales of nucleic acid extraction equipment and reagents, disposable virus sampling tubes, laboratory disinfection equipment and related procurement activities (within the scope of qualification permit).

Note: The authentication scope shall not include the scope of products and services that have not obtained the relevant administrative licenses and qualification licenses approved by the government.

First Issue Date：Dec 01, 2020

Issue On：Dec 01, 2020

Validity Date：Nov 30, 2023

Information about this certificate is available on the official website(www.cnca.gov.cn) of National Certification and AccreditationAdministration of PRC.The validity of this certificate is maintained by annual supervision in a supervision period.This certificate can only be valid if it is combined with the approval notice issued by thecertification institution.To check the valid status of this certificate, please visit our website www.zjlhbjrz.com or www.cnca.gov.cn, or scan 2-dimensional bar code.

中际连横认证

签发：

ZhongjiLianheng (Beijing) Certification Co., LTD

Address: Room 309, Tianjian Building, No. 6, Huixin Nanli, Chaoyang District, Beijing

Postal Code: 100029

Verified Supplier Certificate
认证供应商证书

Verified Supplier Certificate

Verified

Certificate Number: 20979507_P+T

Presented to

BioTeke Corporation (Wuxi) Co., Ltd

无锡百泰克生物技术有限公司

For details, please refer to http://enbioteke.en.alibaba.com

Onsite assessment was conducted for BioTeke Corporation (Wuxi) Co., Ltd by TÜV Rheinland

Assessed by Hui Zhu on 11 Nov. 2020. Valid from: 12 Nov. 2020, Valid until: 11 Nov. 2021.

Signature: _____

Title: Vice President Of Systems TÜV Rheinland Greater China

Alibaba.com

TÜVRheinland®
Precisely Right.

Verified Supplier Certificate
认证供应商证书

Verified

Verified Supplier Certificate

Certification No. 20979507_P+T

BioTeke Corporation (Wuxi) Co., Ltd

无锡百泰克生物技术有限公司

http://enbioteke.en.alibaba.com

Onsite assessment of the following areas was conducted by TÜV Rheinland.

☑ Company Overview	☑ Human Resources
☑ Current Export Situation	☑ Export Business Capacity
☑ Production Capacity	☑ Quality Assurance
☑ Production Process Management	☑ R & D Capacity
☑ Company Development / Expansion Plans	☑ Production Flow
☑ Certification & Photos	☑ Company and Product Samples

Valid: 12 Nov. 2020 to 11 Nov. 2021

Issued by: Alibaba.com

Assessed by: TÜVRheinland® Precisely Right.

Date of Issue: 11 Nov. 2020

Certification No. 20979507_P+T

Signature:

Title: Vice President Of Systems TÜV Rheinland Greater China