Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 0P171016.JBBTQ23

Technical Construction File no. TJS201710132133

Certificate's Holder:	Jinan Biobase Biotech Co., Ltd. Room 501, Tianqiao District Technology Center, No. 6 Lanxiang Middle Road, Tianqiao District, Jinan
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved
Product:	Centrifuge
Model(s):	(see the following annex I)
Verification to:	Standard: EN 61326-1:2013, EN 61000-6-1:2007, EN 61000-6-3:2007+A1:2011+AC:2012, EN 61010-1:2010, EN 60204-1:2006+A1:2009+AC:2010 related to CE Directive(s): 2014/35/EU (Low Voltage) 2014/30/EU (Electromagnetic Compatibility)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:

We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE *Marking Certification Procedure* and to perform all the necessary activities, as required by the Directive before placing the CE Mark on the product(s).

Date of issue 16 October 2017

Expiry date 15 October 2022

Chief Manager
Marco Morino

Digitally signed by Jighili Tatiana
Date: 2021.10.19 12:40:27 EEST
Reason: MoldSign Signature
Location: Moldova

Deputy Manager
Amanda Payne

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Annex I

No. 0P171016.JBBTQ23

Technical Construction File no. TJS201710132133

Model(s): Mini-4K, Mini-6K, Mini-7K, Mini-10K, Mini-10K+, Mini-15K, Mini-4610K, Mini-4610KII, Mini-4KH, Mini-6KH, Mini-10KH, LC-HD, LC-4KII, LC-H4KII, LC-4KA, LC-4K-2, LC-5K, LC-4KB, LC-4KC, LC-T4K, LC-H4K, BKC-TL4,BKC-TL4II, BKC-TL4III, BKC-TL4IV, BKC-TL5VII, BKC-TL5III, BKC-TL5IV, BKC-TL5, BKC-TL5II, BKC-TL6, BKC-TL6II, BKC-TL4V, BKC-TL5VI, BKC-TL5V, BKC-TL6III, BKC-TL6IV, BKC-TL6V, BKC-TL5L, BKC-TL5LII, BKC-TL5RIV, BKC-TL6R, BKC-TL8R, BKC-VL5R, BKC-VL6R, BKC-VL8R, BKC-TL5R, BKC-TL5RII, BKC-TL5RIII, BKC-TL5RL, BKC-VL6RLII, BKC-VL6RL, BKC-VL7RL, BKC-VL8RL, BKC-MH16, BKC-TH16, BKC-TH18, BKC-TH16II, BKC-TH18II, BKC-TH21, BKC-TH18R, BKC-TH18RII, BKC-TH23R, BKC-TH16R, BKC-TH20R, BKC-TH16RII, BKC-TH20RII, BKC-TH12R, BKC-TH16RIII, BKC-TH20RIII, BKC-TH24RII, BKC-VH20R, BKC-VH21RII, BKC-TH23RII, BKC-TH24R, BKC-TH24RL, BKC-VH20RII, BKC-VH21RL, BKC-VH10RL, BKC-TH20RL, BKC-TH21RL, BKC-GC12, BKC-GC24, BKC-PCR16, BKC-PRP5, BKC-MF5A, BKC-MF5B, BKC-MF5C, BKC-AU4, BKC-AU5, BKC-AU5R, BKC-BB6, BKC-BB6A, BKC-BB7, BKC-HC12A, BKC-TB12, BKC-TB4K, BKC-OIL5VII

Ente Certificazione Macchine Srl
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☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

CERTIFICATE

ATTESTATION CERTIFICATE OF MACHINERY AND ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been inspected and audit has been completed successfully.

2006/42/EC Machinery Directive 2014/30/EU Electromagnetic Compatibility Directive and 2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name : **Jinan Biobase Biotech Co., Ltd.**

Company Address : No.51 South Gongye Road, Jinan, Shandong, China 250101

Related Directives and Annex : **2006/42/EC Machinery Directive**
2014/35/EU Low Voltage Directive
2014/30/EU Electromagnetic Compatibility Directive

Related Standards : **EN ISO 12100:2010, EN 60204-1:2006+A1:2009+AC:2010**
EN 61010-1:2010, EN 61326-1:2013

Product Name : **Low Temperature Freezer**

Report No and Date : TELMJ201810082771

Product Brand/Model/Type : BDF-25H150, BDF-25H200, BDF-25H300, BDF-25H389, BDF-25H525, BDF-25V259, BDF-25V450, BDF-25V268, BDF-25V270, BDF-25V328, BDF-40V253, BDF-40V288, BDF-40V288A, BDF-40V525, BDF-40V450, BDF-40V90, BDF-40V270, BDF-40V268, BDF-40V328, BDF-40H100, BDF-40H200, BDF-40H300, BDF-40H390, BDF-40H485, BDF-60H58, BDF-60H118A, BDF-60H218, BDF-60H318, BDF-60H458, BDF-86V158, BDF-86V340, BDF-86V936, BDF-86V100, BDF-86V108, BDF-86V308, BDF-86V528, BDF-86V540, BDF-86V388, BDF-86V398

Certificate Number : **M.2018.201.N7086**
Initial Assessment Date : 17.10.2018
Registration Date : 18.10.2018
Reissue Date/No : -
Expiry Date : 17.10.2023

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

CERTIFICATE

ATTESTATION CERTIFICATE OF ELECTROMAGNETIC COMPATIBILITY AND LOW VOLTAGE DIRECTIVES

Technical file of the company mentioned below has been observed and audit has been completed successfully.
2014/30/EU Electromagnetic Compatibility Directive and
2014/35/EU Low Voltage Directives have been taken as references for these processes

Company Name	: MEDFUTURE LLC
Company Address	: 3231 Osgood Common,Fremont,CA,USA 94539
Related Directives and Annex	: 2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compatibility Directive
Related Standards	: EN 61010-1:2010;EN 61326-1:2013
Product Name	: Laminar Flow Cabinet
Report No and Date	: TELMJ2018010422741;MAKA18010422741
Product Brand/Model/Type	: L-H-13,L-H-18,L-H-11,L-H-15,L-V-13,L-V-18,L-V-680,L-V-880,L-V-SS, L-V-DS,L-V-SD,L-V-DD,L-V-500,B-I-7,PCR-8,PCR-10,PCR-12,PCR-13, PCR-15
Certificate Number	: M.2018.201.N2837
Initial Assessment Date	: 05.01.2018
Registration Date	: 08.01.2018
Reissue Date/No	: -
Expiry Date	: 07.01.2023

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

The validity of the certificate can be checked through www.udem.com.tr. The CE mark shown on the right can only be used under the responsibility of the manufacturer with the completion of EC Declaration of Conformity for all the relevant Directives. This certificate remains the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named firm must keep a copy of this certificate for 15 years from the registration of certificate. This certificate only covers the product(s) stated above and UDEM must be noticed in case of any changes on the product(s)

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.
ADD: No.51 South Gongye Road, Jinan, China250100
TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully
2014/35/EU Low Voltage Directive and 2014/30/EU Electromagnetic Compatibility Directive have been taken as reference for these processes

Company Name:	**Biobase Biodustry(Shandong) Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Band:	**BIOBASE**
Related Directives and Annex:	**2014/35/EU Low Voltage Directive (LVD)** **2014/30/EU Electromagnetic Compatibility (EMC)**
Related Standards:	**EN 61326-1:2013; EN 61010-1:2010**
Poduct(s):	**Balance**
Type(s)/Model(s):	**See Annex**
Classification:	**Laboratory Equipment**
Examination Period:	November 4, 2019
Date of Expiry:	November 3, 2024
Review Result:	We, Biobase Biodustry(Shandong) Co., Ltd., declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Low Voltage Directive 2006/42/EC and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: **2019**

CE

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: BKSD-191141

BIOBASE

Biobase Biodustry(Shandong) Co., Ltd.
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E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

echnical file of the company mentioned below has been inspected and audit has been completed successfully

2014/35/EU Low Voltage Directive and 2014/30/EU Electromagnetic Compatibility Directive have been taken as reference for these processes

Annex

Type(s)/Model(s)	BA604C; BA1004C; BA1204C; BA1604C; BA2004C; BA2204C; BA1003C; BA2003C; BA3003C; BA1004N; BA1104N; BA1204N; BA2004N; BA2104N; NA2204N; BA504B; BA604B; BA1004B; BA1104B; BA1204B; BA1604B; BA2004B; BA2204B; BA2104B;BA2104B; BP1003B; BP1203B; BP2003B; BP3003B; BP4103B; BP5003B; BP10003; BP1003P; BP2003P; BP12002; BP21002; BP31002; BP50002; BP21001; BP31001; BP41001; BP51001; BP61001; BE1002; BE2002; BE3002; BE4002; BE5002; BE6002; BE10002; BE20002; BE30002; BE50002; BE2001; BE4001; BE5001; BE6001; BE8001; BE10001; BE16001; BE20001; BE30001; BE40001; BE50001; BE60001; BE80001; BE100001; BE150001; BE200001; BE300001; BE1000; BE2000; BE3000; BE6000; BE10000; BE15000; BE20000; BE30000; BE1002G; BE2002G; BE3002G; BE6002G; BE10002G; BE20002G; BE30002G; BE40002G; BE50002G; BE60001GF; BE100001GF; BE150002GF; BE6000GF; BE10000GF; BE15000GF; BE1002N; BE2002N; BE3002N; BE5002N; BE6002N; BE10002N; BE3001N; BE6001N; BE10001N; BE20001NF; BE30001NF; BE50001NF; BM-50-10; BM-50-5; BM-50-1; BA-100D; BA-200D

Year of DOC marking: **2019**

Signed for and on behalf of

Company: **Biobase Biodustry(Shandong) Co., Ltd.**

General Manager: Robert Wang

Doument No: BKSD-191141

CE

Version BKSD2019 LVD & EMC DOC 1.0

BIOBASE

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DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully
Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU have been taken as reference for these processes

Company Name:	**Biobase Biodustry (Shandong) Co.,Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Related Directives and Annex:	**2014/35/EU Low Voltage Directive (LVD)** **2014/30/EU Electromagnetic compatibility (EMC)**
Related Standards:	**EN 61010-1:2010; EN 61326-1:2013**
Product(s):	**Hotpate Magnetic Stirrer**
Type(s)/Model(s):	MS7-H550-Pro, MS7-H550-S, MS-H-Pro+, MS-H-Prot, MS-H-S, MS-H280-Pro
Classification:	Laboratory Equipment
Examination Period:	September 17, 2018
Date of Expiry:	September 18, 2023
Review Result:	We, Biobase Biodustry (Shandong) Co.,Ltd, declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of the Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: **2018**

Signed for and on behalf of
Company: **Biobase Biodustry (Shandong) Co.,Ltd.**

General Manager: Robert Wang

Document No: BKSD-1809172

CE

BIOBASE

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EU DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully
Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU have been taken as reference for these processes

Manufacturer:	**Biobase Biodustry (Shandong) Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Related Directives:	**2014/35/EU Low Voltage Directive (LVD)** **2014/30/EU Electromagnetic compatibility (EMC)**
Harmonised Standards:	**EN 61010-1:2010; EN 61326-1:2013**
Product(s):	**Vortex Mixer/Microplate Mixer/Roller Mixer/Rotating Mixer**
Type(s)/Model(s):	MX-S, MX-F, MX-M, MX-T6-S, MX-T6-Pro, MX-RD-E, MX-RD-Pro, MX-RL-E, MX-RL-Pro
Classification:	Laboratory Equipment
Examination Period:	January 29, 2019
Date of Expiry:	January 28, 2024
Review Result:	We, Biobase Biodustry (Shandong) Co., Ltd, declare that during the self-testing and performance evaluation, no non-compliance according to the requirements of the Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: **2019**

Signed for and on behalf of
Company: **Biobase Biodustry (Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: BKSD-1901299

CE

Certificate of Registration

nqa

兹证明

山东博科生物产业有限公司

统一社会信用代码：9137018179889855X7

经营地址：山东省济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园（办公、研发、生 产）；山东省济南市工业南路 51 号（生产、销售）；山东省济南市章丘明水经济开发区鑫岳工业园 8#（研发、生产）

注册地址：山东省济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园

的质量管理体系适用于

体外诊断试剂盒（用于蛋白检测的试剂、用于糖类检测的试剂、用于酶类检测的试剂、用于脂类检测的试剂、用于无机离子类检测的试剂、用于自身抗体检测的试剂、用于其他生理、生化或免疫功能指标检测的试剂）、生物安全柜、医用气溶胶吸附器、压力蒸汽灭菌器、血液冷藏箱、微生物恒温培养箱、全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、全自动生化分析仪、传染病员运送负压隔离舱、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪的的研发、生产和销售（资质许可范围内）

已经 NQA 根据标准

ISO 9001:2015

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
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
SNQA 查询网站：www.snqa.com.cn

Managing Director

Certificate Number **45013**

Date: 09 July 2018
Reissue Date: 16 November 2020
Valid Until: 09 July 2021
EAC Code: 13/19

UKAS MANAGEMENT SYSTEMS
015

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

Certificate of Registration

This is to certify that the Quality Management System of

Biobase Biodustry (Shandong) Co., Ltd.

Unified Social Credit Code: 9137018179889855X7

Operation Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China(Office, R&D, Production);No.51, South Gongye Road, Jinan City, Shandong Province, China(Production, Sale); 8# Xinyue Industrial Park, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China(R&D, Production)

Registered Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China

applicable to

R&D, production and sales of in vitro diagnostic kits (reagents for protein detection, reagents for sugar detection, reagents for enzyme detection, reagents for lipid detection, reagents for inorganic ion detection, reagents for autoantibody detection, reagents for the detection of other physiological, biochemical or immunological indicators), biosafety cabinet, air purifier, pressure steam sterilizer, blood bank refrigerator, microbial incubator, automated ELISA processor, diluent for hematology analyzer, hemolysin for hematology analyzer, ELISA microplate washer, laboratory refrigerator, automatic chemistry analyzer, infectious patients transporting negative pressure isolation chamber, automatic chemiluminescence analyzer, nucleic acid extraction instrument and automatic nucleic acid extraction instrument (within the scope of qualification)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number **45013**

Date: 09 July 2018

Reissue Date: 16 November 2020

Valid Until: 09 July 2021

EAC Code: 13/19

UKAS MANAGEMENT SYSTEMS 015

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Certificate of Registration

nqa.

兹证明

山东博科生物产业有限公司

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注册地址：山东省济南市章丘明水经济开发区经十东路与明埠路交界山东博科产业园

的质量管理体系适用于

体外诊断试剂盒（用于蛋白检测的试剂、用于糖类检测的试剂、用于酶类检测的试剂、用于脂类检测的试剂、用于无机离子类检测的试剂、用于自身抗体检测的试剂、用于其他生理、生化或免疫功能指标检测的试剂）、生物安全柜、医用气溶胶吸附器、压力蒸汽灭菌器、血液冷藏箱、微生物恒温培养箱、全自动酶免工作站、血细胞分析用稀释液、血细胞分析用溶血剂、洗板机、医用冷藏箱、全自动生化分析仪、传染病员运送负压隔离舱、全自动化学发光测定仪、核酸提取仪、全自动核酸提取仪的的研发、生产和销售（资质许可范围内）

已经 NQA 根据标准

ISO 13485: 2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
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
SNQA 查询网站：www. snqa. com. cn

Managing Director

Certificate Number **45014**

Date: 09 July 2018
Reissue Date: 16 November 2020
Valid Until: 09 July 2021

UKAS MANAGEMENT SYSTEMS
015

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

Certificate of Registration

This is to certify that the Quality Management System of

Biobase Biodustry (Shandong) Co., Ltd.

Unified Social Credit Code: 9137018179889855X7

Operation Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China(Office, R&D, Production);No.51, South Gongye Road, Jinan City, Shandong Province, China(Production, Sale); 8# Xinyue Industrial Park, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China(R&D, Production)

Registered Address: Biobase Biodustry Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui Economic Development Zone, Zhangqiu, Jinan City, Shandong Province, China

applicable to

R&D, production and sales of in vitro diagnostic kits (reagents for protein detection, reagents for sugar detection, reagents for enzyme detection, reagents for lipid detection, reagents for inorganic ion detection, reagents for autoantibody detection, reagents for the detection of other physiological, biochemical or immunological indicators), biosafety cabinet, air purifier, pressure steam sterilizer, blood bank refrigerator, microbial incubator, automated ELISA processor, diluent for hematology analyzer, hemolysin for hematology analyzer, ELISA microplate washer, laboratory refrigerator, automatic chemistry analyzer, infectious patients transporting negative pressure isolation chamber, automatic chemiluminescence analyzer, nucleic acid extraction instrument and automatic nucleic acid extraction instrument (within the scope of qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number **45014**

Date: 09 July 2018

Reissue Date: 16 November 2020

Valid Until: 09 July 2021

UKAS MANAGEMENT SYSTEMS 015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

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