CERTIFICATE

ATTESTATION CERTIFICATE OF MACHINERY AND ELECTROMAGNETIC COMPATIBILITY DIRECTIVES

Technical file of the company mentioned below has been observed

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

Company Name	: Shanghai Baobang Medical Equipment Co., Ltd.
Company Address	: Bldg.15, No.889 Guinan Rd., Songjiang Dist., Shanghai, China 201617
Related Directives and Annex	: 2006/42/EC Machinery Directive 2014/30/EU Electromagnetic Compatibility Directive
Related Standards	: EN ISO 12100:2010, EN 60335-1:2012+A14:2019 EN 55014-1:2017+A11:2020, EN 55014-2:2015 EN IEC 61000-3-2:2019, EN 61000-3-3:2013+A1:2019
Product Name	: Portable Hyperbaric Chamber
Report No and Date	: MD-TCF-210608-31452, TESH21060831453
Product Brand/Model/Type	:ST701, ST702, ST702-1.5, ST801, ST801-3, MP801, ST901, ST901C, ST901-3, ST901-4, ST1001, ST1700, ST2200, MP2200, STM2000, MC4000, MC2021, MC6000, MC9000, MC1000

Certificate Number	: M.2021.206.C65469
Initial Assessment Date	: 11.06.2021
Registration Date	: 15.06.2021
Reissue Date/No	: -
Expiry Date	: 14.06.2026

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

The validity of the certificate can be checked through www.udemltd.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 Co. Ltd. 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

ISTITUTO SERVIZI
EUROPEI TECNOLOGICI

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Cap. soc. i.v. € 10.200,00
Cod. Fisc. e P.IVA 02 332 750 369
Reg. Imprese 02 332 750 369
REA MN 0221098

CERTIFICATE OF COMPLIANCE

Certificado de Conformidade - Сертификат соответствия - Konformitätserklärung

1) APPLICANT:
Xiamen Lidu Pneumatic Equipment Co.,Ltd
466# Huangzhuangli,Guankou Town,Jimei,Xiamen,China

2) CERTIFICATE NO.:
IT1712LD07051805

TCF(S) NO.:
MICEZ-2018050401-EMC
MICEZ-2018050401-LVD

3) WITH REFERENCE TO EC DIRECTIVE APPLIED:
Low Voltage Directive 2014/35/EU
Electromagnetic Compatibility 2014/30/EU

HARMONIZED STANDARDS APPLIED:
EN 60204-1:2006/A1:2009
EN 61000-6-1:2007
EN 61000-6-3:2007/A1:2011/AC:2012

4) CERTIFICATION ISET MARK:
ISTITUTO SERVIZI
EUROPEI TECNOLOGICI

5) PRODUCT CHARACTERISTICS: Refrigerated air dryer

MODEL(S): OD-1A

REMARK: ***The verification has been carried out on a voluntary basis. We attest that a TCF is in place. The product(s) satisfies the requirements of the Certification Mark of ISET, in reference to the above list standard(s). The above compliance mark can be fixed on the product(s) according to the ISET regulation about its release. This verification doesn't imply assessment of the production and the product(s).***

CE

Notice of the CE marking: The label of the CE marking: Not less than 5mm height. Before putting the product(s) into market, CE marking and EC declaration are duties of the manufacturer. The manufacturer is responsible to start the CE marking certification procedure and to perform the activities according to all the relative directive(s).

6) DATE OF ISSUE: 07/05/2023 ***DATE OF EXPIRE:*** 06/05/2028

CERTIFICATION MANAGER:

ISTITUTO SERVIZI EUROPEI TECNOLOGICI
ISET S.R.L

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60146956 0001

Report No.: 17056817 008

Manufacturer:
Foshan MIC Medical Technology
CO., Ltd.
Unit 501-1 and 503, 5th Floor
No. 7 Building, Zone A
Hantian Industrial Park
17th Shenhai Road, Guicheng, Nanhai
Foshan
528200 Guangdong
P.R. China

Products:
- Steam Sterilizers
- Oxygen Concentrators

Replaces Approval, Registration No.: HD 60132938 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-18

Date: 2020-02-18

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Jing Zhang
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®
LGA
Precisely Right.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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CO., Ltd.
Unit 501-1 and 503, 5th Floor
Hantian Industrial Park
17th Shenhai Road, Guicheng, Nanhai
528200 Foshan GUANGDONG
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date February 18, 2020

Application for : **Vollst. QMS, Anhang II MDD**
Certificate No. : HD 60146956 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60146956 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

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LGA Products GmbH

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90431 Nürnberg

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Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
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