Freie und Hansestadt Hamburg
Behörde für Justiz und Verbraucherschutz

Behörde für Justiz und Verbraucherschutz (V44), Postfach 302822, 20310 HH

Shanghai International Holding Corporation
GmbH (Europe)
Liang Jin
Eiffestraße 80
20537 Hamburg

Ministry of Justice and Consumer Protection
V4 - Pharmaziewesen und Medizinprodukte
Medizinprodukte - V44

Postfach 30 28 22
20310 Hamburg

Telefon: +49 40 428 37 - 2120
Zentrale: +49 40 428 28 - 0
E-Fax: +49 40 4279 - 48542
E-Mail: medizinprodukte@justiz.hamburg.de

Ansprechpartner/in: Sylvia Frenzel
Aktenzeichen: G517-80.01/07-01-, 0002

Hamburg, den 11.07.2023

Verordnung (EU) 2017/745 i. V. m. Medizinprodukterecht-Durchführungsgesetz (MPDG)

hier: Freiverkaufszertifikat
Bescheinigung Nummer 0447/2023

Ihr Antrag vom 26.06.2023

Freiverkaufszertifikat	**Free Sales Certificate**
nach Artikel 60 auch i.V.m. Artikel 120 Abs. 3 und Abs. 4 der Verordnung (EU) 2017/745	according to Article 60 even in conjunction with Article 120 para. 3 and para. 4 of Regulation (EU) 2017/745
und § 10 des Medizinprodukterecht-Durchführungsgesetzes	and section 10 of the Medical Devices Law Implementing Act
in der jeweils geltenden Fassung	as amended
zur Vorlage bei den zuständigen Behörden / Stellen des Staates	for presentation to the competent authorities / bodies of the
Argentinische Republik	**Argentine Republic**
Es wird bescheinigt, dass der	It is also certified that the
Bevollmächtigte:	**Authorized Representative:**
Shanghai International Holding Corporation GmbH (Europe) **Eiffestraße 80** **20537 Hamburg**	**Shanghai International Holding Corporation GmbH (Europe)** **Eiffestraße 80** **20537 Hamburg** **Germany**
seine eingetragene Niederlassung in Deutschland hat und dass die gemäß der	has its registered place of business in Germany and the devices bearing the CE marking in accordance with the
Verordnung (EU) 2017/745 **vom 05. April 2017** **über Medizinprodukte**	**Regulation (EU) 2017/745** **of 05 April 2017** **on medical devices**

in der jeweils geltenden Fassung mit einem CE-Kennzeichen versehenen Produkte in der Union gehandelt werden dürfen.	as amended may be marketed in the Union.
Produkt/e: Siehe Anlage, 1 Seite.	**Device/s:** See Annex, 1 page.
Hersteller: Shenzhen MedKe Technology Co., Ltd 4/F, Bldg. A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist. 518126 Shenzhen PEOPLE'S REPUBLIC OF CHINA	**Manufacturer:** Shenzhen MedKe Technology Co., Ltd 4/F, Bldg. A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist. 518126 Shenzhen PEOPLE'S REPUBLIC OF CHINA
Behörde für Justiz und Verbraucherschutz L. S. 104 Hamburg Frenzel	

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land: BUNDESREPUBLIK DEUTSCHLAND

Diese öffentliche Urkunde

2. ist unterschrieben von Frau Frenzel

3. in seiner Eigenschaft als Sachbearbeiterin

4. sie ist versehen mit dem Siegel / Stempel des (der)

Behörde für Justiz und Verbraucher schutz, Nr. 104

Bestätigt

5. in HAMBURG 6. am 01. Aug. 2023

7. durch die BEHÖRDE FÜR INNERES UND SPORT

8. unter Nr. 372/23

9. Siegel / Stempel 10. Unterschrift

Matthies

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 085432 0005 Rev. 03

Holder of Certificate: **Shenzhen MedKe Technology Co., Ltd**
401, 503, Bldg. A1, Anle Ind. Zone
No. 172, Hangcheng RD., Sanwei Community, Hangcheng Street
Baoan District
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Medical Compressors and Nebulizers system, Medical accessories (including SpO2 sensors, Temperature probes, Patient cables and Lead wires, BP accessories and Infusors)**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 085432 0005 Rev. 03

Report No.: GZ2311401

Valid from: 2023-12-01
Valid until: 2026-01-16

Date, 2023-12-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 085432 0005 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Shenzhen MedKe Technology Co., Ltd**
401, 503, Bldg. A1, Anle Ind. Zone, No. 172, Hangcheng RD.,
Sanwei Community, Hangcheng Street, Baoan District, 518126
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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TÜV®

BFZC11085921D01T220511

第 11085921 号

商 标 注 册 证

核定使用商品/服务项目（国际分类：38）

第 38 类：无线电广播；信息传送；电子邮件；电信信息；计算机终端通讯；提供数据库接入服务；提供与全球计算机网络的电讯连接服务；电子公告牌服务(通讯服务)；全球计算机网络访问时间出租；计算机辅助信息和图像传送（截止）

注 册 人 深圳市曼克科技有限公司

注册人地址 广东省深圳市宝安区西乡街道固戍社区航城大道安乐工业区A1栋厂房4楼A

注册日期 2013年12月14日 **有效期至** 2023年12月13日

局 长

发证机关 国家知识产权局

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 085432 0007 Rev. 00

Manufacturer:

Shenzhen MedKe Technology Co., Ltd
401, 503, Bldg. A1, Anle Ind. Zone
No. 172, Hangcheng RD., Sanwei Community, Hangcheng Street
Baoan District
518126 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 085432 0004 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 085432 0007 Rev. 00

Report No.: GZ2311401

Valid until: 2024-01-16

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-12-01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 085432 0007 Rev. 00

Product Category(ies): SpO2 sensors

Description of Change:

Address Change:

Old site address: 4/F, Bldg.A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist., 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

New site address: 401, 503, Bldg. A1, Anle Ind. Zone, No. 172, Hangcheng RD., Sanwei Community, Hangcheng Street, Baoan District, 518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Shan Wang / Zuyin Xian
Shenzhen MedKe Technology Co., Ltd
401, 503, Bldg. A1, Anle Ind. Zone
No. 172, Hangcheng RD., Sanwei Community, Hangcheng Street
Baoan District
518126 SHENZHEN
PEOPLE'S REPUBLIC OF CHINA

via Email: tate@medke.com

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
85432	GZ2211401	michael.ye@tuvsud.com Michael Ye	+86 755 3332 3237	2023-09-08 Dokument1	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 085432 0006 Rev. 00

Reference: GZ2211401

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000019638

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Product Service

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For certificate validity see www.tuvsud.com/ps-cert?q=**CL 085432 0006 Rev. 00.**

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
08th September 2023.

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Ye
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Tunde Junaid
Application Reviewer