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

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

TÜV SÜD Product Service

Certificate

No. Q6 090585 0003 Rev.

Holder of Certificate: **Changzhou Zhengyuan Medical Technology Co., Ltd.**
Northeast 3/4/5 Floor, C1 Block
No.9 Changyang Road
West Taihu Lake International Medical Industrial Park
213145 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Changzhou Zhengyuan Medical Technology Co., Ltd.
Northeast 3/4/5 Floor, C1 Block, No.9 Changyang Road, West Taihu Lake International Medical Industrial Park, 213145 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Production and Distribution of Mesh Nebulizer**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), 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:Q6 090585 0003 Rev.

Report No.: SH2295201

Valid from: 2022-05-23
Valid until: 2025-05-22

Date, 2022-05-23

Christoph Dicks
Head of Certification/Notified Body

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

Changzhou Zhengyuan Medical Technology Co.,Ltd.
Northeast, floor 4, Building C1, West Taihu Medical Industry Incubation Park, No.9 Changyang Road, Wujin District, Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

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TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: SH24952A01

To whom it may concern,

Confirmation of the status of a formal application 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 with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000017953

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

<2024-5-16>

TÜV SÜD Product Service GmbH
Medical and Health Services

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<Jiang Shunnan>

Conformity Assessment Responsible (CARE)

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
Device 1 **Mesh Nebulizer** (Basic UDI-DI:69393136MEN01RM)