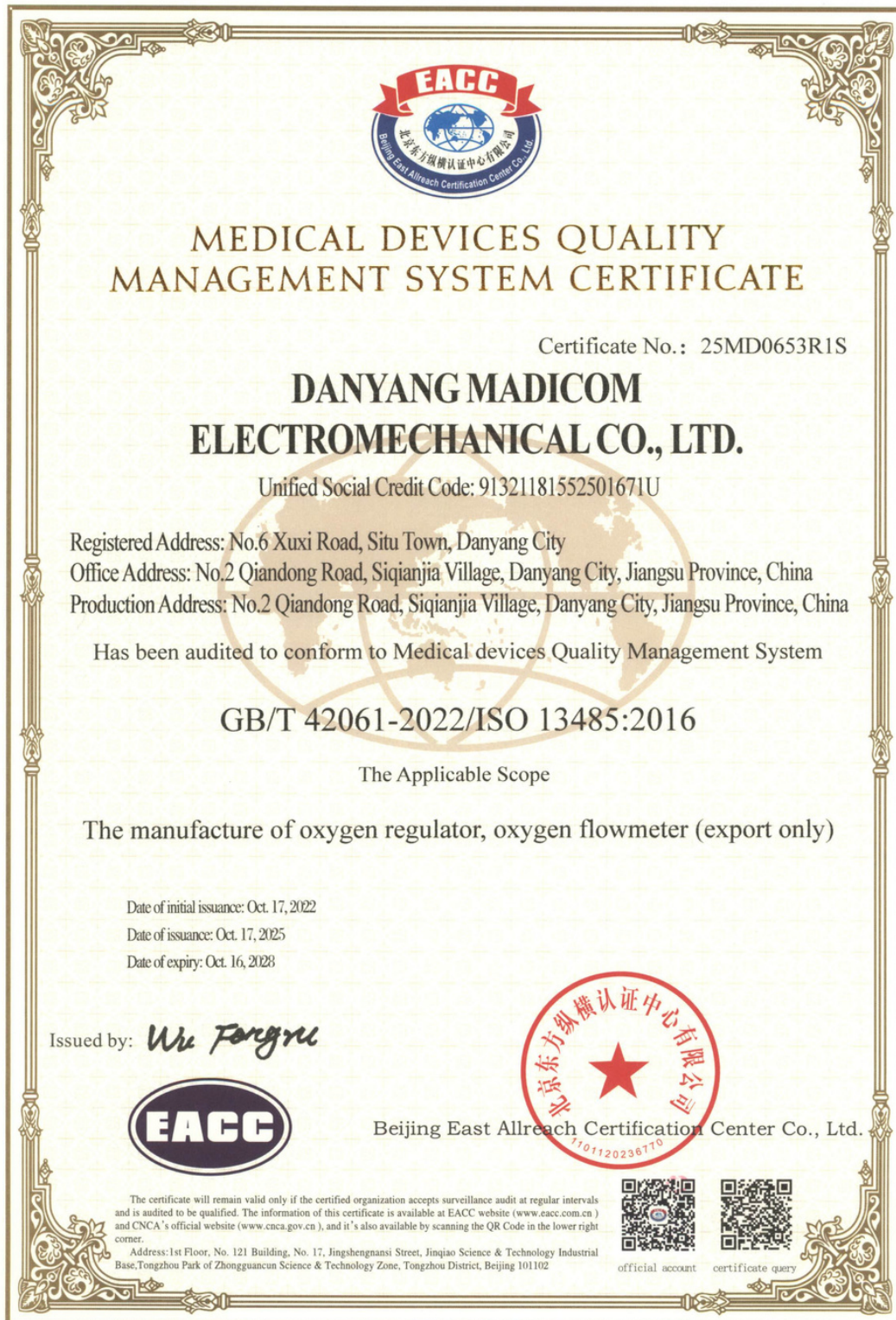


Dispositivos médicos

Equipos de alta confiabilidad para la regulación de presión y vacío, fabricados bajo sistemas de gestión de calidad ISO 13485 y con cumplimiento de los requisitos regulatorios aplicables para dispositivos médicos.





**Fiscal Year 2025
The 3rd Party Report of**

FDA Facility Registration & Listing

Note : This document is Not issued by FDA. We, J F, as a 3rd party, created it to make easier for customer to present information

The following contents, FDA registered establishment & product information, are excerpted from the database at www.fda.gov.

Owner Number Holder:

DANYANG MADICOM ELECTROMECHANICAL CO., LTD.

No. 2 Qiandong Road, SiTu Town, Danyang, JIANGSU , 212300 , CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration.

Registration Number: 3008791328

Owner/Operator Number: 10034964

Device Listing#: See annex

Registration Expiration Date: 2025-12-31

J&F TECHNOLOGY SERVICE has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuant to the Code of Federal Regulation 21 CFR 807, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICE assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICE is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICE

**19838 Moon Shadow Circle
Walnut, California, 91789**

United States



Fiscal Year 2025 FDA DEVICE LISTING

Annex to Report.

Device#	Product Codes	Device Name
D506464	CAT	CANNULA, NASAL, OXYGEN
D506463	BYG	MASK, OXYGEN
D115286	CAN	Regulator, pressure, gas cylinder
D510028	GCY	APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED
D502828	IKY	MATTRESS, FLOTATION THERAPY, NON-POWERED
D478141	KFZ	HUMIDIFIER, NON-DIRECT PATIENT INTERDACE (HOME-USE)
D502836	FNM	Mattress, air flotation, alternating pressure
D296771	CCN	FLOWMETER, NONBACK-PRESSURE COMPENSATED, BOURDON GAUGE
D534271	FOX	STAND, INFUSION
D508966	ECX	Cylinder, compressed gas, and valve

END OF THE ANNEX

✓ **Note²:** To check the Registration & Device listing status of above product(s), search <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

1. click above hyperlink;
2. copy the Owner/Operator Number, paste into the text box;
3. click the SEARCH icon.

Cilindros de Oxígeno



QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00125Q30716R6M/3302

We hereby certify that

Ningbo Zhengxin Fire-fighting Equipment Co., Ltd.

Business Registration Number: 913302017702420231

Registered Address: Gaogao Village, Huangjiahe Town, Yuyao City, Ningbo City, Zhejiang Province, China

Operation Address: Gaogao Village, Huangjiahe Town, Yuyao City, Ningbo City, Zhejiang Province, China (A District of Huangjiahe Zone)

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

ISO 9001:2015

The Quality Management System Applies in the following area:

Design and Production of Approved Aluminum Seamless Gas Cylinders, Gas Cylinder Valves, Export Steel Seamless Gas Cylinders, Fire Extinguishers, Fire-fighting Valves, Hose Reels, Other Fire Parts and Maintenance of Fire Extinguishers

Certified since: February 14, 2007 Valid from: January 24, 2025 Valid until: February 25, 2028

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.

Please access www.cqc.com.cn for checking validity of the certificate.

This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).



谢荣煦
Signed by: Mr. Zhuo



中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No. 198, Nansihuan Xilu, Beijing 100070 P.R. China

<http://www.cqc.com.cn>