tecnamed
Ingeniería S.A.S

Tomas de pared

Nuestros reguladores son fabricados bajo estándares de calidad internacionales, tales como ISO 9001, listado UL.

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 055809 0026 Rev. 00

Manufacturer: **Gentec (Shanghai) Corporation**
No. 499 Wenji Road
Songjiang District
201616 Shanghai
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012841

Authorized Representative:
MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 055809 0026 Rev. 00

Report No.: SH2438703
Valid from: 2025-06-25
Valid until: 2030-06-24

Issue date: 2025-06-25

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

VXHT.SA13031 - Station Inlets and Outlets

Station Inlets and Outlets

See General Information for Station Inlets and Outlets

PACIFIC HOSPITAL SUPPLY CO LTD SA13031
4TH FL
160 DAYE RD
BEITOU DISTRICT
TAIPEI, 112 TAIWAN
Station outlets/inlets for use in medical gas systems distributing oxygen, vacuum, nitrous oxide, air, nitrogen or carbon dioxide in hospitals in rigid piping systems at pressures not exceeding 100 psig (200 psig nitrogen).

DISS

Gas Service	DISS Wall	DISS Console	DISS Ceiling	DISS Ceiling Column
Oxygen	104, 410, 470	070, 103	—	—
Vacuum	104, 410, 470	070, 103	—	—
Nitrous Oxide	104, 410, 470	070, 103	—	—
Medical Air	104, 410, 470	070, 103	—	—
Nitrogen	104, 410, 470	070, 103	—	—
Evacuation	104, 410, 470	070, 103	—	—
Carbon Dioxide	104	103	—	—
I-Air	104	103	—	—

Oxequip

Gas Service	Wall	Console	Ceiling	Ceiling Column
Oxygen	—	700	—	—
Vacuum	—	700	—	—
Nitrous Oxide	—	700	—	—
Medical Air	—	700	—	—

Chemetron

Gas Service	Wall	Console	Ceiling	Ceiling Column
Oxygen	094	093	—	—
Vacuum	094	093	—	—
Nitrous Oxide	094	093	—	—

Medical Air	094	093	—	—
Evacuation	094	093	—	—
Carbon Dioxide	094	093	—	—
I-Air	094	093	—	—

Ohmeda

Gas Service	Wall	Console	Ceiling	Ceiling Column
Oxygen	472	072	—	—
Vacuum	472	072	—	—
Nitrous Oxide	472	072	—	—
Medical Air	472	072	—	—
Nitrogen	472	072	—	—
Evacuation	472	072	—	—

Japanese

Gas Service	Wall	Console	Ceiling	Ceiling Column
Oxygen	—	500	—	—
Vacuum	—	500	—	—
Nitrous Oxide	—	500	—	—
Medical Air	—	500	—	—

Last Updated on 2021-02-03

2019

CERTIFICATE OF REGISTRATION

This certifies that:

Pacific Hospital Supply Co., Ltd
No. 8, Tongke 2nd Road
Tongluo Township Miaoli, TAIWAN (CHINA) 366

is registered with the U.S. Food and Drug Administration for FY 2019 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3014615028**
U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

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Registrar Corp

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Russell K. Statman
Executive Director
Registrar Corp
Dated: January 14, 2019