



Certificate

No. Q5 098746 0007 Rev. 03

Holder of Certificate: **Exact Medical Manufacturing, Inc**
No. 21 Qingjiang Road, Xinbei District
213000 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and development, production and distribution of sterile surgical gown, sterile surgical drape, sterile equipment cover, sterile surgical pack, intraoperative probe cover and sterile ultrasound gel.**

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, 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:Q5 098746 0007 Rev. 03

Report No.: SH26117801
Valid from: 2026-09-19
Valid until: 2029-09-18

Date, 2026-08-21

Christoph Dicks
Head of Certification/Notified Body



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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): **Exact Medical Manufacturing, Inc**
No. 21 Qingjiang Road, Xinbei District, 213000 Changzhou,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Design and development, production and distribution of
sterile surgical gown, sterile surgical drape, sterile equipment
cover, sterile surgical pack, intraoperative probe cover and sterile
ultrasound gel.

Exact Medical Manufacturing, Inc
No. 101 Huashan Road, XinBei District, 213000 Changzhou City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Production of sterile surgical gown, sterile surgical drape, sterile
equipment cover, sterile surgical pack, intraoperative probe cover
and sterile ultrasound gel.