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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q5 088684 0004 Rev. 00

Holder of Certificate: **Nanjing Leji Medical Equipment Co., Ltd.**
B4, No.15 Wanshou Road
Pukou Economic Development Zone
211800 Nanjing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Nanjing Leji Medical Equipment Co., Ltd.
B4, No.15 Wanshou Road, Pukou Economic Development Zone,
211800 Nanjing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Anesthesia Machines, Ventilators,
ENT Treatment Units, Medical Air-
compressors,
Sputum Elimination Machines**

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1885105

Valid from: 2019-05-22

Valid until: 2022-01-06

Date, 2019-05-22

Stefan Preiß
Head of Certification/Notified Body