



# Certificate

No. Q5 030821 0010 Rev. 00

**Holder of Certificate:** **Leica Microsystems Ltd. Shanghai**  
Floor 1, 2, 3A, 4A, and 6, Building T20-1, 258 Jinzang Road  
China (Shanghai) Pilot Free Trade Zone  
201206 Shanghai  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production,  
Service and distribution of Microscopes /  
Accessorial Equipment (Clinical Purpose)  
and IVD Instrument for Specimen Preparation**

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 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:Q5 030821 0010 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 030821 0010 Rev. 00)

**Report No.:** SH2142501

**Valid from:** 2021-12-02

**Valid until:** 2024-01-31

**Date,** 2021-12-02



Christoph Dicks  
Head of Certification/Notified Body

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

**Facility(ies):** Leica Microsystems Ltd. Shanghai  
Floor 1, 2, 3A, 4A, and 6, Building T20-1, 258 Jinzang Road, China  
(Shanghai) Pilot Free Trade Zone, 201206 Shanghai, PEOPLE'S  
REPUBLIC OF CHINA

See Scope of Certificate

Leica Microsystems Ltd. Shanghai  
Room 301, Building T20-5, 258 Jinzang Road, China (Shanghai)  
Pilot Free Trade Zone, 201206 Shanghai, PEOPLE'S REPUBLIC  
OF CHINA

Distribution of Microscopes /Accessorial Equipment (Clinical  
Purpose) and IVD Instrument for Specimen Preparation