



Certificate

No. Q5 030821 0010 Rev. 01

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 and Service, and Distribution of Biological Microscopes/ Accessories (In Vitro Diagnostic Purpose), IVD Instrument for Specimen Preparation and Image scanning and analysis system for microscopic observation of human tissue specimen.**

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. 01

Report No.: SH2342501

Valid from: 2024-02-01

Valid until: 2027-01-31

Date, 2023-10-13

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): **Leica Microsystems Ltd. Shanghai**
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Design and Development, Production, Service and Distribution of
Biological Microscopes/Accessories (In Vitro Diagnostic Purpose),
IVD Instrument for Specimen Preparation and Image scanning and
analysis system for microscopic observation of human tissue
specimen.

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 Biological Microscopes/Accessories (In Vitro
Diagnostic Purpose), IVD Instrument for Specimen Preparation
and Image scanning and analysis system for microscopic
observation of human tissue specimen.

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