



Certificate

No. Q5 051867 0016 Rev. 03

Holder of Certificate: **Lucky Healthcare Co., Ltd.**
No.6 Lekai South Street
071054 Baoding, Hebei
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Lucky Healthcare Co., Ltd.**
No.6 Lekai South Street, 071054 Baoding, Hebei, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of
Medical Dry Film, Medical X-ray Film, Medical Thermal Film,
Medical Transparent Film, Print Film for Medical Use and
Medical Thermal Print Media
Production and Distribution of Medical Dry Imager**

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). 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_051867_0016_Rev_03

Report No.: SH2329701

Valid from: 2023-04-24

Valid until: 2026-03-31

Date, 2023-04-24



Christoph Dicks

Head of Certification/Notified Body