DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 051867 0016 Rev. 01

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Medical Films, 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). See also notes overleaf.

Digitally signed by Palii Nina
Date: 2023.02.20 14:18:35 EET
Reason: MoldSign Signature
Location: Moldova

Report No.: SH1929702

Valid from: 2020-04-01
Valid until: 2023-03-31

Date, 2020-03-03

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

Product Service

认 证 证 书

证书号. Q5 051867 0016 Rev. 01

证书持有者：

乐凯医疗科技有限公司

中华人民共和国河北省保定市乐凯南大街6号 071054

生产场地：

乐凯医疗科技有限公司

中华人民共和国河北省保定市乐凯南大街6号 071054

认证标志：

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

认证范围：

医用胶片的设计和开发、生产和分销
医用图像打印机的生产和分销

认证标准：

EN ISO 13485:2016
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2016)
DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

报告号： SH1929702

生效期： 2020-04-01

有效期： 2023-03-31

发证日期, 2020-03-03

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD

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本证书是由具有法律效力的英文证书翻译而来

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