

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 106030**

Certificate Holder: **Huqiu Imaging (Suzhou) Co., Ltd.**
Unified Social Credit Code: 91320505MA1N9Q2B24
Registration Address: Building 22, No.369, Lu Shan Road,
Suzhou Hi-tech Park, 215129 Jiangsu, P.R. China
Operation Address: same as above

Scope: Design and Manufacturing of Dry Imager, Self-Service Kiosk,
Medical X-Ray Film Processor, Image Developer,
Thermal Wide-format Printer

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-08-14 until 2022-08-24.
It remains valid subject to satisfactory surveillance audits.
First certification 2010
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2020-08-17



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com





Certificate

No. Q5 095431 0001 Rev. 00

Holder of Certificate: **Huqiu Imaging (Suzhou) Co., Ltd.**
Building 22, No. 369 Lushan Road, New District
215129 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Huqiu Imaging (Suzhou) Co., Ltd.
Building 22, No. 369 Lushan Road, New District, 215129 Suzhou,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Medical Dry Imager, Self-Service Kiosk for
Medical Dry Film, Medical Dry Film,
Medical X-ray Film Processor

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.: SH20164101

Valid from: 2020-07-23

Valid until: 2023-07-22

Date, 2020-07-23

Christoph Dicks
Head of Certification/Notified Body



Professionals in Medical Imaging

The HQ-450DY Dry Imager is a thermo-graphic film processor designed to copy and send images through DICOM network protocol. It uses the latest direct dry thermal imaging technology which accommodates for a full range of modalities including CT, MRI, DR, CR, Digital Gastrointestinal, Nuclear Medicine, Mobile X-Ray Imaging, and Dentistry, etc. The HQ-Series Dry Imager dedicates to precision in diagnosis with its outstanding image quality, and offers affordable imaging catering to your needs.



HQ-450DY Dry Imager

Affordability is compatible with quality

Specifications	
Print Technology	Direct thermal (dry, daylight-load film)
Spatial Resolution	320dpi (12.6 pixels/mm)
Throughput	14"×17" ≥80 sheets/h; 8"×10" ≥100 sheets/h
Grayscale Contrast Resolution	14 bits
Film Transferring Method	Rubbing
Film Tray	Two supply tray, 200-sheet capacity total
Film Sizes	8"×10", 10"×12", 11"×14", 14"×17"
Applicable film	Medical Dry Thermal Film (blue or clear base)
Interface	10/100/1000 Base-T Ethernet (RJ-45)
Network Protocol	Standard DICOM 3.0 connection
Image Quality	Automatic calibration using built-in densitometer
Control Panel	Touch Screen, Online Display, Alert, Fault and Active
Power Supply	100-240VAC 50/60Hz 600W
Weight	50Kg
Operating Temperature	5°C-35°C
Storage Humidity	30%-85%
Storage Temperature	-22°C-50°C
Base Holding	Optional

Note: All data above are subjected to change without prior notice.

Huqiu Imaging (Suzhou) Co., Ltd

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 Tel: +86-512-66368881 Fax: +86-512-66367771 Website: www.hu-q.com/en
 E-mail: export@hu-q.com

Huqiu Imaging reserves the right to modify product models, specifications and design anytime without prior
 Huqiu Imaging reserves the right of final explanation for all information displayed in this catalogue.

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

IMAGE Information Systems Europe GmbH
Lange Straße 16
18055 Rostock
Germany

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection, installation and servicing of
• **Digital image processing systems**

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-02-22

Expiry date: 2024-02-15

Report No.: 3420FS18F

Procedure No.: QS – 3420

Certificate No.: 3420GB445210222A

Hamburg, 2021-02-22



MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a DAKKS accredited management systems
certification body



Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

PD-730-165 EC Declaration of Conformity

The manufacturer IMAGE Information Systems Europe GmbH
Lange Str. 16
18055 Rostock, Germany
Tel.: +49 381 496 58 20
www.image-systems.biz | info@image-systems.biz

declares under its sole responsibility that the medical device stated as follows:

iQ-VIEW/PRO 3.1

is classified as **Class IIa** according to rules **10** and **16** of the Medical Device Directive 93/42/EEC, Annex IX.

The conformity assessment has been performed according to Annex II (4) of MDD 93/42/EEC based on the following elements:

- Conformity to the Essential Requirements according to Annex I of MDD 93/42/EEC
- Quality Management System for the products / product categories

Digital image processing systems

The license of certification is subject to surveillance by the Notified Body.

MEDCERT GmbH
Pilatuspool 2
20355 Hamburg, Germany
(Notified Body CE 0482)

Rostock, 2018-04-12


Dr. Arpad Bischof
Managing Director