EC CERTIFICATE

Certificate No 1925/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

ALMAX IMAGING SRL

24121 BERGAMO (BG) - PASSAGGIO CANONICI LATERANENSI 12/10C (ITA) - Italy

manages in the factory of:

24060 SAN PAOLO D'ARGON (BG) - VIA ABATE SALVIONI 10 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Electronic control unit for radiologic use

Mobile X-ray equipment

X-ray system, fixed working station

C-arms, radiographic/fluoroscopic units

Type ref. as to document Annex 1 to ALMAX TF Rev: 02 dated 2019-02-22; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16-0005497-01; DM17-0015492-01; DM18-0023281-01; DM18-0025091-01; DM18-0026870-01; DM19-0037088-01; DM20-0048625-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Digitally signed by Trocin Caterina
Date: 2021.06.25 11:47:00 EEST
Reason: MoldSign Signature
Location: Moldova

Date:	2017-03-27
Updated:	2020-02-24
Substitution Date:	2019-06-11
Expiry Date:	2022-03-26

DocuSign

IMQ

Ref Doc : Annex 1 to ALMAX TF

Rev: 02 date 22-02-2019

Company : Almax Imaging S.r.l

Reference IMQ certificate : 1925/MDD

Trade mark / Marca: ITALRAY

***Product List** / Elenco Prodotti:*

***"C" arms, radiographic/fluoroscopic units** /* Stativo da corsia arco a "C"

***Modd.:*CARMEX R9; CARMEX S9; CARMEX R12; CARMEX S12**

***Mobile x-ray equipment** / Stativi da corsia*

Modd.: **CORSIX; CORSIX R; CORSIX DR; CORSIX R DR;**
CORSIX ENERGY; CORSIX R ENERGY

2020-02-24

CSQ MED

www.imq.it

CISQ is a member of IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. **9124.AMX2**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

ALMAX IMAGING SRL

VIA SANTA ELISABETTA 5 - 24121 BERGAMO (BG)

UNITA' OPERATIVE
OPERATIVE UNITS

VIA LOCATELLI 13F - 24020 RANICA (BG)

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

Progettazione e produzione di apparecchiature medicali per radiologia
Design and production of radiological medical devices

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2017-02-10	2017-02-10	2020-02-10

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28; in caso contrario, il presente certificato cesserà la propria validità in tale data
The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28; otherwise the validity of this certificate will expire

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SQG N°005A, SGA N°006D, SCR N°005F
SSI N°003G, FSM N°007I, SGE N°006M
EMAS N°003P, PRD N°005B, PRS N°080C,
ISP N°063E, LAB N°0121, LAT N°021
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC20QY20038R2M/46500

We hereby certify that

Jusha Display Technology Co., Ltd.

(This Main Certificate Contains 2 Sub-certificates)

Unified Social Credit Code: 9132010667492893XP

Nanjing Jusha Display Technology Co., Ltd:
Registered Address: Unit A, 8F, Building 01, No.301 Hanzhongmen Street, Gulou District, Nanjing, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Nanjing Jusha Commercial&Trading Co., Ltd.:
Registered Address：301 Room, No.301 Hanzhongmen Street, Gulou District, Nanjing, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Nanjing Jusha Medical Technology Co., Ltd.
Registered Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China
Business Address：No.99 Yaogu Avenue, Nanjing Jiangbei New Area, Jiangsu Province, China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

YY/T 0287-2017 / ISO 13485:2016

The Quality Management System Applies in the following area:

Nanjing Jusha Display Technology Co., Ltd.: Design, Development and Manufacture of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales And Services of Imported Medical Instruments (Within the Scope of Qualification License)
Nanjing Jusha Commercial & Trading Co., Ltd.: Sales of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales and Services of Imported Medical Instruments (Within the Scope of Qualification License)
Nanjing Jusha Medical Technology Co., Ltd.: Sales of Professional High-Resolution Displays, High Pressure Injector, Digital X-Ray Medical Imaging Systems, Non-Woven Wraps, Sales and Services of Imported Medical Instruments (Within the Scope of Qualification License)

Certified since: September 29, 2014 Valid from: July 24, 2020 Valid until: September 28, 2023

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.

Signed by: Lu Mei

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

D 0006766

2018年版

EC Declaration of Conformity

Manufacturer:

Nanjing Jusha Display Technology Co., Ltd.
8A, Block1. Nanjing International Service Outsourcing Mansion, No. 301 Hanzhongmen Street, Nanjing City, Jiangsu Province, 210036 China.
Tel: +0086-25-83305050
Fax: +0086-25-83302899

whose single Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
Tel：+31644168999
E-mail：peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Medical Display

Model：M550G, M550, JUSHA-M550G, JUSHA-M550

UMDNS-Code: **17960**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to **class I according to Annex IX of the Directive 93/42/EEC of European Union**. It bears the mark

CE

The product concerned has been manufactured following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Nanjing Jusha Display Technology Co., Ltd.
Address: 8A, Block1. Nanjing International Service Outsourcing Mansion, No. 301 Hanzhongmen Street, Nanjing City, Jiangsu Province, 210036 China.

Nanjing 2020-10-28

Place, date

Legally binding signature, Function

MED CERT®

Certification. Medical Only.

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

DAkkS 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