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

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

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

CERTIFICATO CE

Certificato n. 2059/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

ITALRAY SRL

50018 SCANDICCI (FI) - VIA DEL PARLAMENTO EUROPEO 9/D (ITA) - Italy

mantiene nello stabilimento di:

50018 SCANDICCI (FI) - VIA DEL PARLAMENTO EUROPEO 9/D (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Sistemi di acquisizione ed elaborazione immagini radiologiche

Apparecchiature mobili per radiologia

Apparecchi radiologici per mammografia

Tavolo radiologico per uso generico

Modd. come da documento "allegato al Certificato CE 2059/MDD - Elenco Dispositivi" rev. 02 del 26/05/2020; valido solo se provvisto del timbro IMQ.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM19-0038734-01; DM20-0051295-01; DM20-0048628-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2019-11-12
Data aggiornamento:	2020-06-10
Sostituisce:	2020-04-15
Data scadenza:	2022-04-12

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IMQ

EC CERTIFICATE

Certificate No 2059/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:

ITALRAY SRL

50018 SCANDICCI (FI) - VIA DEL PARLAMENTO EUROPEO 9/D (ITA) - Italy

manages in the factory of:

50018 SCANDICCI (FI) - VIA DEL PARLAMENTO EUROPEO 9/D (ITA) - Italy

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

X-ray Image acquisition and processing systems

Mobile radiographic units

Mammography X-ray equipment

General purpose X-ray examination table

Type ref. As to document "2059/MDD EC Certificate Annex - Devices List" rev. 02 dated 2020/05/26; 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:

DM19-0038734-01; DM20-0051295-01; DM20-0048628-01.

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.

Date:	2019-11-12
Updated:	2020-06-10
Substitution Date:	2020-04-15
Expiry Date:	2022-04-12

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IMQ

Allegato al Certificato CE 2059/MDD- Elenco Dispositivi

2059/MDD EC Certificate Annex - Device List

rev. 02 del 26/05/2020
rev. 02 dated 2020/05/26

Marca *Trade mark*:	**ITALRAY srl**

Categoria di prodotto: *Product category:*	**Sistemi di acquisizione ed elaborazione immagine radiologiche** *X-ray image acquisition and processing systems*
Modelli: *Type ref:*	**X-FRAME DR EZ;** **X-FRAME DR EZ@;** **X-FRAME DRF;** **X-FRAME DRF@.**

Categoria di prodotto: *Product category:*	**Apparecchiature mobili per radiologia** *Mobile radiographic units*
Modello: *Type ref:*	**XFM.**

Categoria di prodotto: *Product category:*	**Tavolo radiologico per uso generico** *General purpose x-ray examination table*
Modelli: *Type reff:*	**CLINODIGIT OMEGA.**

Categoria di prodotto: *Product category:*	**Apparecchi radiologici per mammografia** *Mammography X-ray equipment*
Modelli: *Type reff:*	**MAMMOGRAPH;** **MAMMOGRAPH FFDM;** **MAMMOGRAPH D-TOMO.**

Timbro IMQ
IMQ stamp

2020-06-10

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.* 1405.2019

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

ITALRAY SRL

VIA DEL PARLAMENTO EUROPEO 9/D - 50018 SCANDICCI (FI)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA DEL PARLAMENTO EUROPEO 9/D - 50018 SCANDICCI (FI)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, commercializzazione, installazione e assistenza post-vendita di prodotti nel settore della diagnostica per immagini nel campo della radiologia
Design, manufacture, placing on the market, trade, installation and after-sale service of products in the area of diagnostic by X-ray images

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 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*
	2019-08-07	2019-08-07	2022-08-06

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

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

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.