



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

IMQ DocuSign



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



 IMQ DocuSign

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: <i>Product category:</i>	Sistemi di acquisizione ed elaborazione immagine radiologiche <i>X-ray image acquisition and processing systems</i>
Modelli: <i>Type ref:</i>	X-FRAME DR EZ; X-FRAME DR EZ@; X-FRAME DRF; X-FRAME DRF@.
Categoria di prodotto: <i>Product category:</i>	Apparecchiature mobili per radiologia <i>Mobile radiographic units</i>
Modello: <i>Type ref:</i>	XFM.
Categoria di prodotto: <i>Product category:</i>	Tavolo radiologico per uso generico <i>General purpose x-ray examination table</i>
Modelli: <i>Type ref:</i>	CLINODIGIT OMEGA.
Categoria di prodotto: <i>Product category:</i>	Apparecchi radiologici per mammografia <i>Mammography X-ray equipment</i>
Modelli: <i>Type ref:</i>	MAMMOGRAPH; MAMMOGRAPH FFDM; MAMMOGRAPH D-TOMO.

Timbro IMQ
IMQ stamp



2020-06-10



www.imq.it

CERTIFICATO N. 1761.2019
CERTIFICATE N.

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 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, immissione in commercio, commercializzazione, installazione ed 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 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 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
	2002-01-28	2019-11-11	2022-12-12

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

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

CISQ is a member of



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.*



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19, 29

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



Organismo di Certificazione Federato CISQ
www.imq.it



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.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ has issued an IQNet recognized certificate that the organization:

ITALRAY SRL

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

has implemented and maintains a

Quality Management System

for the following scope:

Design, manufacture, placing on the market, trade, installation and after-sale service of products in the area of diagnostic by X-ray images

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: 2019 - 11 - 11

Expires on: 2022 - 12 - 12

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126254



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



www.imq.it

CERTIFICATO N. **1405.2019**
CERTIFICATE N.

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

CISQ is a member of



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.



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



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

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CISQ is the Italian Federation of management system Certification Bodies.

DICHIARAZIONE DI CONFORMITÀ CE

prevista all'Allegato VII della Direttiva 93/42/CEE, modificata dalle Direttive 98/79/CE, 2000/70/CE, 2001/104/CE, 2007/47/CE e dal Regolamento CE 1882/2003

Adamo S.r.l. – P.I.: IT 02454830817, in qualità di Fabbricante

DICHIARA

sotto la propria responsabilità che i prodotti

MARCA:

HORUS

MODELLI:

SERIE HS 100-200-300-400-500-600-800-1000

appartenenti alla **Classe I**

secondo le regole di classificazione di cui all'Allegato IX della Direttiva 93/42/CEE, modificata dalle Direttive 98/79/CE, 2000/70/CE, 2001/104/CE, 2007/47/CE e dal Regolamento CE 1882/2003,

soddisfano tutti i requisiti applicabili della direttiva

93/42/CEE

modificata dalle Direttive 98/79/CE, 2000/70/CE, 2001/104/CE, 2007/47/CE, dal Regolamento CE 1882/2003, recepita dal D.lgs. 24.02.1997, n.46 emendato col D.lgs. 25.01.2010, n.37 e recepimento della Direttiva 2007/47/CE

e delle seguenti Norme armonizzate di riferimento:

**CEI EN 60601-1 3^a edizione – IEC 60601-1-2 – IEC 60127-1
IEC 60320-1 – IEC 60417 – IEC 60529:A1 – IEC 60950-1
ISO 14971**

Il Fascicolo Tecnico comprovante la conformità dichiarata è depositato presso la sede della
Adamo S.r.l. – Via F. Culcasi, 1/B – 91100 TRAPANI (TP) – ITALY
Tel. +39 0923 558778 – Fax +39 0923 534026 – info@adamosrl.com



Trapani, 31 Gennaio 2019



Giacomo Adamo
Amministratore Unico
Adamo S.r.l.



CERTIFICATO n. **26356**
CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

ADAMO S.r.l.

IT - 91100 TRAPANI (TP) - VIA FRANCESCO CULCASI 1/B Z.I.R.

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 91100 TRAPANI (TP) - VIA FRANCESCO CULCASI 1/B Z.I.R.

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI EN ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES **SETTORE** **IAF 19, 29**
CODE

Progettazione e sviluppo, produzione, distribuzione ed assistenza tecnica di
apparecchiature elettromedicali.
*Design and development, production, distribution of and technical support for
electromedical equipment.*

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 THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE **24/10/2018**
FIRST ISSUE
DATA DELIBERA **24/10/2018**
DECISION DATE
DATA SCADENZA **23/10/2021**
EXPIRY DATE
EMISSIONE CORRENTE **24/10/2018**
ISSUE DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



SGQ n. 008 A SSI N. 007 G
SGA n. 001 D SGE N. 001 M
SCR n. 002 F ISP N. 006 O
FSM n. 006 I EMAS N. 008 P
PRD n. 008 B ITX N. 004 L
DAP n. 003 H
PRS n. 100 C

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

C01 ED 03 010616

CISQ is a member of



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.

For information concerning the validity
of the certificate, you can visit the site
www.certiquality.it

The validity this certificate depends
on annual audit and on a complete
review every three years of the
Management System.



www.cisq.com

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Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.



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

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China

<http://www.cqc.com.cn>

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

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



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