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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.

CERTIFICATE N. 9124.IRR2
CERTIFICADO N.

**WE HEREBY CERTIFY THAT THE MANAGEMENT SYSTEM OPERATED BY
CERTIFICAMOS QUE EL SISTEMA DE GESTIÓN DE**

IRE RAYOS X, S.A.

C/ ISLA DE LA PALMA 22 BIS - 28703 SAN SEBASTIAN DE LOS REYES (MADRID) SPAIN

OPERATIVE UNITS / INSTALACIÓN DE

C/ ISLA DE LA PALMA 22 BIS - 28703 SAN SEBASTIAN DE LOS REYES (MADRID) SPAIN

IS IN COMPLIANCE WITH THE STANDARD / REÚNE LOS REQUISITOS DE LA NORMA

ISO 13485:2016

FOR THE FOLLOWING ACTIVITIES / PARA LAS SIGUIENTES ACTIVIDADES

Sales and technical assistance of diagnostic medical devices. Design and development, sales, installation and maintenance of software for diagnostic medical imaging

Venta y asistencia técnica de equipos con fines de diagnóstico médicos. Diseño y desarrollo, venta, instalación y mantenimiento de software para diagnóstico de imágenes médicas

*Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization
Cualquier aclaración adicional relativa a la aplicación de la norma ISO 13485:2016, puede obtenerse consultando a la organización*

**THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS
EL PRESENTE CERTIFICADO ESTÁ SUJETO AL RESPETO DEL REGLAMENTO
PARA LA CERTIFICACIÓN DE LOS SISTEMAS DE GESTIÓN**

DATES:	FIRST CERTIFICATION PRIMERA CERTIFICACIÓN	CURRENT ISSUE EMISION ACTUAL	EXPIRY VÁLIDO HASTA
	2011-05-09	2020-03-11	2023-05-14

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



SGQ N° 005 A

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

The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years
La validez del certificado está sujeta a auditorías anuales y a la recertificación completa del Sistema de Gestión con una periodicidad trienal



Organismo di Certificazione Federato CISQ
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**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:

IRE RAYOS X, S.A.

C/ ISLA DE LA PALMA 22 BIS - 28703 SAN SEBASTIÁN DE LOS REYES (MADRID) SPAIN

has implemented and maintains a

Quality Management System

for the following scope:

Sales and technical assistance of diagnostic medical devices. Design and development, sales, installation and maintenance of software for diagnostic medical imaging

Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 13485:2016

Issued on: 2020 - 03 - 11

Expires on: 2023 - 05 - 14

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 - 130900



*Alex Stoichitoiu
President of IQNET*



*Ing. Mario Romersi
President of CISQ*

IQNet Partners*:

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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com