



EC CERTIFICATE

Certificate No 736/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:

VILLA SISTEMI MEDICALI SPA

20090 BUCCINASCO (MI) - VIA DELLE AZALEE 3 (ITA) - Italy

manages in the factory of:

20090 BUCCINASCO (MI) - VIA DELLE AZALEE 3 (ITA) - Italy

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

Fluoroscopic/radiographic tables

X-ray image systems

X-ray systems

Mobile fluoroscopic/radiographic units

Mobile radiographic units

Type ref. As to document "736/MDD EC Certificate Annex - Devices List" rev. 1 dated 2020/01/15; 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:

10AE00021; 10AE00124; 10AF00071; 10AF00195; 10AH00030; 10AI00012; 10AI00013; 10AI00222; 10AJ00041; 10AK00074; 10AK00210; 10AM00111; 10AN00084; 10AO00002; 10AN00125; DM15A0536216-01; DM15A0524865-01; 10AO00173; DM16-0004419-01; DM16-0002181; DM17-0010457-01; DM19-0037201-01; DM20-0048685-01.

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: 2004-04-01
Updated: 2020-02-04
Substitution Date: 2019-04-05
Expiry Date: 2022-09-21

IMQ

DocuSign





Allegato al Certificato CE 736/MDD - Elenco Dispositivi

736/MDD EC Certificate Annex - Devices List

rev. 1 del 15/01/2020
rev. 1 dated 2020/01/15

Marca: Trade mark:	Villa Sistemi Medicali
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Categoria di prodotto: Product category:	Tavoli fluoroscopici/radiografici Fluoroscopic/radiographic tables
Modello: Type ref:	APOLLO; APOLLO DRF; APOLLO EZ; APOLLO EZ DRF

Categoria di prodotto: Product category:	Sistemi per radiologia con intensificatore di immagini e catena televisiva X-ray image systems
Modello: Type ref:	IB SYSTEMS

Categoria di prodotto: Product category:	Sistemi per radiologia X-ray systems
Modello: Type ref:	MOVIPLAN iC

Categoria di prodotto: Product category:	Apparecchiature mobili per radiologia con intensificatore di immagini e catena televisiva Mobile fluoroscopic/radiographic units
Modello: Type ref:	ARCOVIS 3000 R; ARCOVIS 3000 S

Categoria di prodotto: Product category:	Apparecchiature mobili per radiologia Mobile radiographic units
Modello: Type ref:	VISITOR T4; VISITOR T30 C; VISITOR T30 C-DR; VISITOR T30 M; VISITOR T30 M-DR; VISITOR T30 R; VISITOR T30 R-DR; VISITOR T40 M; VISITOR T40 M-DR



2020-02-04

1/1





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

VILLA SISTEMI MEDICALI SPA
VIA DELLE AZALEE 3 - 20090 BUCCINASCO (MI)

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: 2018 - 09 - 11

Expires on: 2020 - 05 - 28

*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 - 36934



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.

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



www.imq.it

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.

CERTIFICATO N. 9120.VLS1
CERTIFICATE N.

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

VILLA SISTEMI MEDICALI SPA

VIA DELLE AZALEE 3 - 20090 BUCCINASCO (MI)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA DELLE AZALEE 3 - 20090 BUCCINASCO (MI)

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 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 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
	1998-03-27	2018-09-11	2020-05-28

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



www.cisq.com



IAF: 19, 29

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

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



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CERTIFICATO N. 9124.VLS2
CERTIFICATE N.

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

VILLA SISTEMI MEDICALI SPA

VIA DELLE AZALEE 3 - 20090 BUCCINASCO (MI)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA DELLE AZALEE 3 - 20090 BUCCINASCO (MI)

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
1998-03-27

EMISSIONE CORRENTE
CURRENT ISSUE
2018-07-11

SCADENZA
EXPIRY
2020-05-29

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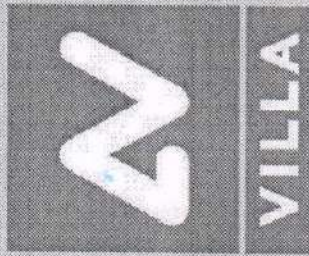
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CISQ is the Italian Federation of management
system Certification Bodies.



certificate of attendance

We certify that

**Mr. Lungu Ion of
S.A. M-INTER-FARMA Company**

Has successfully attended the Sales Technical training for Visitor
T30 M-DR and Moviplan series
On 13 January 2020.

Milan, 13 January, 2020



Firmato digitalmente da: Mauro Scilligo
Data: 17/03/2020 13:34:24

Mauro Scilligo
Sales & Marketing Director
Villa Sistemi Medicali SpA