



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; 10.K00074; 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



This Approval Certificate is subjected to the provisions laid down in the "IMQ regulation for the certification of Medical Devices - CE Marking - Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

IMQ S.p.A. | I-20138 Milano
| Via Quintiliano 43 |
www.imq.it

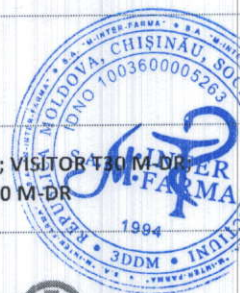


Allegato al Certificato CE 736/MDD - Elenco Dispositivi

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
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

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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. 9124.VLS2
CERTIFICATE N.

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

2020-05-13

SCADENZA
EXPIRY

2023-05-29

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



www.cisq.com



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 revisione 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
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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.