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:

Fluoroscophic/radiographic tables

X-ray image systems

X-ray systems

Mobile fluoroscophic/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.

Digitally signed by Morozov Maria
Date: 2020.05.19 12:41:59 EEST
Reason: MoldSign Signature
Location: Moldova

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

DocuSign

IMQ

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

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.

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9124.VLS2**

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*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-03-27	2018-07-11	2020-05-29

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

REPUBLICA MOLDOVA, CHIŞINĂU, SOCIETATEA PE ACTIUNI
IDNO 1003600005263
S.A. M·INTER FARMA 1994
3DDM

IMQ

FEDERAZIONE CISQ

ACCREDIA
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

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.

Letter of Authorization

To tender Committee IMSP SR Balți:

To Whom It May Concern:

We, **VILLA SISTEMI MEDICALI SPA**, located in Italy – Buccinasco – Via delle Azalee 3, herewith authorize **M-INTER-FARMA**, located at str. Grenoble 23, Chisinau, MD2025, Republic of Moldova, as follows:

- As our **Exclusive Authorized Representative** to participate in Public Tender No. ocds-b3wdp1-MD-1586428920723 (ID: 21021980) on 18 May 2020, and, subsequently, to negotiate and to sign the Contract, to make delivery, installation, to train the personnel of the end user for work with the equipment, and to perform warranty and after warranty service for the provided VILLA SISTEMI MEDICALI SPA products in the Republic of Moldova.
- Is approved in correspondence with the conditions of directive 93/42/EEC to perform The Notification/Registration of medical devices to the Agency of the Medical Products and Medical Devices and the inclusion in the Register of the medical devices manufactured by US (medical X-ray equipment) , in territory of Republic of Moldova.
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices manufactured by VILLA SISTEMI MEDICALI SPA in the Republic of Moldova, and to perform Essential Duties associated with such equipment as required by Moldovan Law No. 102 09.06.2017 regarding medical devices.

This Authorization letter is valid until December 31, 2025 or till conclusion of all contracts.

Date ____ _____ 2020 stamp Signature

Digitally signed by:Mauro Scilligo
Date:14/04/2020 14:25:09

Villa Sistemi Medicali SpA
Via delle Azalee, 3
20090 Buccinasco - Italy

Capitale sociale € 3.315.000
C.F. - P.IVA 10022080153
R.E.A. MI 1337218 - R.I. MI

Tel. +39 02 488591
Fax +39 02 4881844
Fax +39 02 48859206

www.villasm.com
vsminfo@villasm.com
direzione@pec.villasm.com

The Manufacturer's Declaration

To tender Committee IMSP SR Balți:

To Whom It May Concern:

We, **VILLA SISTEMI MEDICALI SPA,** located in Italy – Buccinasco – Via delle Azalee 3, declare the following:

- **M-INTER-FARMA S.A.**, located at str. Grenoble 23. mun. Chişinau MD2025, Republic of Moldova, is the authorized and certified service center in RM for pre-sale, service, and post-sales service and maintance of the equipment by VILLA SISTEMI MEDICALI SPA.
- As the manufacturer, we guarantee our products against defects in materials and workmanship, and provide services based on the standard terms and conditions of our warranty policy.

This Declaration Letter is valid until 31th December, 2025, or till conclusion of all contracts.

Date ____ _____ 2020 stamp Signature

Digitally signed by:Mauro Scilligo
Date:14/04/2020 14:25:42

Villa Sistemi Medicali SpA
Via delle Azalee, 3
20090 Buccinasco - Italy

Capitale sociale € 3.315.000
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Fax +39 02 48859206

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direzione@pecvillasm.com

VILLA

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