

TO WHOM IT MAY CONCERN

Whereas ANTONIO MATACHANA, S.A who are established and reputable manufacturers of Infection Control equipments, with headquarters in Calle Almogàvers 174-176, 08018 Barcelona (Spain),

do hereby certify that the company Echipamed PLUS ERL, with business address at Valea Trandafirilor, 24B, of.80 – MD-2001 Chisinau, Republic of Moldova.

They are fully authorised to perform after sales activities (quote, sell spare parts) as well carry out maintenance activities in Moldova.

This sole agency agreement will be valid until 7th of January 2021.

And in proof of this, we hereunder sign the present certificate in the city of Barcelona, on the 7th of January 2020.

ANTONIO MATACHANA, S.A.


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Servicio Técnico Internacional
Service & Support
Raurell, 21-29 Nave 4
Poligono Industrial Camí Real
Castelldefels (Barcelona)

Ramón Torres

Technical Manager Europe & USA





Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

ANTONIO MATACHANA, S.A.
C/ Almogàvers, 174
08018 Barcelona
Spain

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standard:

ISO 9001:2015

The Quality Management Systems applicable to:

Design and manufacture of sterilizers, disinfection devices and treatment equipment for medical devices, food, associated research, industry, medical waste and pharmaceutical laboratories. Distribution of communities, surgical, sterilisation, disinfection and mortuary equipment. Technical Service and Validation Service for sterilization processes, for washing and thermal disinfection, and for heat sealing of sterilization packaging.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Approval
Certificate No: SGI 3945738

Original Approval: 25 July 1995
Current Certificate: 14 September 2018
Certificate Expiry: 31 October 2021

Issued by: LRQA España, S.L.U.
For and on behalf of: Lloyd's Register Quality Assurance Limited



001

C/ Princesa, 29 – 1º - 28008 Madrid, España

For and on behalf of 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA

The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Macro Revision 14



CERTIFICATE SCHEDULE

ANTONIO MATACHANA, S.A. C/ Almogàvers, 174 08018 Barcelona Spain

Main Location

ANTONIO MATACHANA, S.A.
C/ Almogàvers, 174
08018 Barcelona
Spain

Activities

Design and manufacture of sterilizers, disinfection devices and treatment equipment for medical devices, food, associated research, industry, medical waste and pharmaceutical laboratories. Distribution of communities, surgical, sterilisation, disinfection and mortuary equipment.

Other Locations

ANTONIO MATACHANA, S.A.
C/ Copernic, 8
08860 Castelldefels, Barcelona
Spain

MATACHANA FRANCE, S.A.S.
(GRUPO MATACHANA, S.A.)
Europarc, 5, Allée des Saules
94043 Créteil Cedex
France

ANTONIO MATACHANA, S.A.
C/ Raurell, 21-29, Nave 4
08860 Castelldefels, Barcelona
Spain

Activities

Design and manufacture of sterilizers, disinfection devices and treatment equipment for medical devices, food, associated research, industry, medical waste and pharmaceutical laboratories.

Commercial activities and after sales service.

Technical Service and Validation Service for sterilization processes, for washing and thermal disinfection, and for heat sealing of sterilization packaging.

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Matrix Revision: 14

Certificate

Standard **ISO 50001:2011**

Certificate Registr. No. **01 407 1419339**


Certificate Holder: **Antonio Matachana, S.A.**
Copèrnic, 8
E - 08860 Castelldefels

Scope: Design and manufacture of sterilizers for medical devices, food, associated research, industry and pharmaceutical laboratories

Proof has been furnished by means of an audit that the requirements of ISO 50001:2011 are met.

Validity: The certificate is valid from 2018-01-10 until 2021-01-09.
First certification 2015

2018-03-01


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

DECLARACIÓN DE CONFORMIDAD CE

EC DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITÉ CE

La empresa: ANTONIO MATACHANA, S.A.
The company: Almogàvers, 174
La société: E-08018 – Barcelona

Declara bajo su única responsabilidad que el equipo,
Declares that, in its own responsibility, the equipment
Déclare sous sa propre responsabilité, que l'appareil,

Marca: Matachana **Tipo:** Esterilizador de vapor.
Brand / Marque: Matachana *Type / Tipe:* Steam sterilizer / Stérilisateur à la vapeur d'eau.

Serie: S1000 **Modelos:** S1004 V-1, S1006 V-1, S1008 V-1, S1010 V-1, S1012 V-1,
Series / Série *Models / Modèles:* S1004 E-1, S1006 E-1, S1008 E-1, S1010 E-1, S1012 E-1,
S1004 V-2, S1006 V-2, S1008 V-2, S1010 V-2, S1012 V-2,
S1004 E-2, S1006 E-2, S1008 E-2, S1010 E-2, S1012 E-2

siendo productos en el ámbito de la Directiva Europea 93/42/CEE por la que se regulan los productos sanitarios y clasificado como clase IIb según la regla 15 del Anexo IX,
Being devices within the scope of the regulation of the European Directive 93/42/EEC concerning Medical Devices (MDD), and classified as Class IIb according to rule 15 of Annex IX therein,
étant dispositifs dedans le champ d'application de la Directive Européenne 93/42/CEE relative aux dispositifs médicaux, et classifié comme Classe IIb selon la règle 15 de l'Annexe IX,

se hallan en conformidad con:
conforms to / sont conformes à:

- **Directiva 93/42/CEE relativa a los Productos Sanitarios, Anexo I.**
- *Directive 93/42/EEC concerning Medical Devices, Annex I.*
- *Directive 93/42/CEE relative aux dispositifs médicaux, Annexe I.*

Evaluación de la conformidad según:

Conformity assessment according to: / Évaluation de la conformité selon:

- **Directiva 93/42/CEE relativa a los Productos Sanitarios, Anexo II excepto II.4**
- *Directive 93/42/EEC concerning Medical Devices, Annex II without II.4*
- *Directive 93/42/CEE relative aux dispositifs médicaux, Annexe II à l'exception du II.4*

Con número de registro HD 60029459 0001 del Organismo Notificado Europeo:
Under the Registration number *from the European Notified Body number:*
Avec registre numéro *de l'Organisme Notifié Européen :*

TÜV Rheinland LGA Products GmbH
An Grauen Stein
D-51105 Köln



Además de la Directiva de Productos Sanitarios 93/42/CEE los productos mencionados o sus componentes cumplen con los requisitos esenciales de las siguientes Directivas que son relevantes:
Additionally to the Medical Device Directive 93/42/EEC the a. m. devices or the included components fulfil the essential requirements of the following relevant Directives:
En addition à la Directive relative aux Dispositifs Médicaux 93/42/CEE les dispositifs mentionnes si dessus les exigences essentielles des suivantes Directives relevantes:

EMC 2004/108/EC, LVD 2006/95/EC, MD 2006/42/EC, PED 97/23/EC

Estando disponibles las correspondientes Declaraciones o Certificados de Conformidad emitidos por los fabricantes.

Respective Declarations or Certificates of Conformity issued by the manufacturers are available.
Étant disponibles les respectives Déclarations ou Certifications de Conformité livrés par les fabricants

Nombre: Jose Carlos López **Ramón Calvera**
Sagué
Name / Nom:

Cargo: Director Industrial **Director de Calidad**
Title / Position:

Lugar y fecha: Barcelona, 14 de mayo de 2010
Place and date / lieu et date:

ANTONIO MATACHANA, S.A.
Calle Hierro, 20-22
E-08038 Barcelona - SPAIN
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Fax + 34.93 223 33 84