

TO WHOM IT MAY CONCERN

Whereas ANTONIO MATACHANA, S.A who are established and reputable manufacturers of Infection Control equipments, with headquarters in Calle Almogávares 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 10th of January 2023.

And in proof of this, we hereunder sign the present certificate in the city of Barcelona, on the 10th of January 2022.

ANTONIO MATACHANA, S.A.



Ramón Torres

Technical Manager Europe & USA

●●● matachana
Servicio Técnico Internacional
Service&Support
Raurell, 21-29 Nave 4
Poligono Industrial Camí Rai
08860-Castelldefels (Barcelona)



Certificate of Approval

This is to certify that the Management System of:

Antonio Matachana, S.A.

Almogavares, 174-176, 08018 Barcelona, Spain

has been approved by Lloyd's Register to the following standards:

ISO 9001:2015

Approval number(s): ISO 9001 – 0036999

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.

The scope of this approval is 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 and validation service at customer's premises (sterilizers, washer-disinfectors and sealing machines).



Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: Lloyd's Register Quality Assurance España, S.L.U.

for and on behalf of: Lloyd's Register Quality Assurance Limited



Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1297087-1

Organization: ANTONIO MATACHANA, S.A.
Almogàvers 174
08018 Barcelona
Spain

Scope: Design and development, manufacture, distribution, installation and servicing of sterilizers and disinfection devices.

Distribution of equipment for sterilization and disinfection.

Validation service for sterilization process with moist heat and low temperature steam and formaldehyde (LTSF) for washing and thermal disinfection processes and for heat sealing processes of packaging for terminally sterilized devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92603406-40

Effective date: 2021-02-17

Expiry date: 2022-02-17

Issue date: 2021-02-17

J. Pyclik



Jaroslav Pyclik
TÜV Rheinland LGA Products GmbH
Erlanger Straße 2 · 90431 Nürnberg · Germany

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 **Antonio Matachana, S.A.** 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: