

TO WHOM IT MAY CONCERN

Whereas ANTONIO MATACHANA, S.A who are established and reputable manufacturers of Infection Control equipments, with headquarters in Calle Copèrnic, 8 08860 Castelldefels (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 2024.

And in proof of this, we hereunder sign the present certificate in the city of Barcelona, on the 16th of March 2023.

ANTONIO MATACHANA, S.A.



Ramón Torres

Technical Manager Europe & USA

 **matachana**

ANTONIO MATACHANA, S.A.
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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

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	ANTONIO MATACHANA, S.A. Almogàvers 174 08018 Barcelona Spain	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.
/02	ANTONIO MATACHANA, S.A. Copèrnic, 8 08860 Castelldefels (Barcelona) Spain	Design, development and manufacture of sterilizers and disinfection devices.
/03	ANTONIO MATACHANA, S.A. Raurell, 27-29, Nave 4 08860 Castelldefels (Barcelona) Spain	Quality assurance, installation, service and validation service.

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J. Pyclick

Jaroslav Pyclick
TÜV Rheinland LGA Products GmbH
Ellystraße 2 · 90431 Nürnberg · Germany

EC CONFORMITY CERTIFICATE

The manufacturer Antonio Matachana, S.A., located at Carrer Almogàvers, 174, E-08018 Barcelona (Spain), CERTIFIES that the steam sterilizers Matachana brand, S1000 series, models:

1004V-1	1006V-1	1008V-1	1010V-1	1012V-1
1004V-2	1006V-2	1008V-2	1010V-2	1012V-2
1004E-1	1006E-1	1008E-1	1010E-1	1012E-1
1004E-2	1006E-2	1008E-2	1010E-2	1012E-2

being products within the scope of the European Directive 93/42/EEC concerning medical devices and classified to class IIb according to the rule 15 of the Annex IX, are in conformity with:

- Directive 93/42/EEC concerning medical devices, Annex I, according to the harmonized standard:

EN 285

- The more specific essential health and safety requirements of the Annex I of the Directive 2006/42/EC on machinery, according to the following harmonized standards:

EN ISO 12100

EN 60204-1

The conformity assessment according to Directive 93/42/EEC concerning medical, Annex II except II.4, with registration number HD 60144134 0001 from the European Notified Body TÜV Rheinland LGA Products GmbH located at Tillystrasse 2, D-90431 Nürnberg, allows to fix on each manufactured product, the CE0197 marking and to draw up the related EC conformity declaration.

- Directive 2014/68/EU concerning pressure equipment according to the following harmonized standards:

EN 14222

and German design code AD-2000:

AD 2000 Merkblatt

The conformity assessment according to Directive 2014/68/EU concerning pressure equipment, module B+C2 (EU-type examination-production type + conformity to type), with certificate number ATI/EP-Bp/B08967/19 from the European Notified Body TÜV SÜD ATISAE, S.A.U. located in Avda. de los Artesanos, 20, E-28760 Tres Cantos Madrid (Spain), allows to fix on each manufactured product, the CE0053 marking and to draw up the related EC conformity declaration.

- Essential requirements set out in Annex I of the European Directive 2014/30/UE relating to electromagnetic compatibility according to the following standard:

EN 61326-1

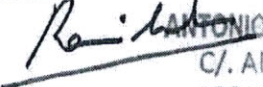
- Principal elements on the safety objectives set out in Annex I of the European Directive 2014/35/UE relating to electrical equipment designed for use within certain voltage limits according to the following standards:

EN 61010-1

EN 61010-2-040

- Additionally, these products comply with the European Directive 2011/65/UE on restriction of the use of certain hazardous substances in electrical and electronic equipment.

Barcelona, October 15th, 2021


ANTONIO MATACHANA, S. A.
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08018 - BARCELONA
Ramón Calvera Sagué
ANTONIO MATACHANA, S.A.
Director of Quality and of Research & Technology

NOTE: For undated normative references, the latest edition of the referenced document (including any amendments) applies.

