

Barcelona, March 12th, 2025

TO WHOM IT MAY CONCERN

Whereas **ANTONIO MATACHANA, S.A** who are established and reputable manufacturers of Infection Control equipment, with headquarters in C/ Copèrnic, 8 08860 Castelldefels – Barcelona (Spain), do hereby certify that the company

**Echipamed Plus SRL,
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau**

is our distributor in Moldova and in therefore authorized by us to offer, sell, deliver, install, repair and service Matachana equipment in Moldova.

This sole agency agreement will be valid until the 31st of December 2025; renewable in written form, under mutual approval.

And in proof of this, we hereunder sign the present certificate in the city of Barcelona, on the 12th March 2025.



ANTONIO MATACHANA, S.A

Mr. Manuel Matachana

CEO



Certificate of Approval

This is to certify that the Management System of:

Antonio Matachana, S.A.

C/ Copérnic, 8, 08860 Castelldefels, Barcelona, Spain

has been approved by LRQA 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, manufacture and final testing of sterilizers, disinfection and treatment equipment for medical devices, food, research, industry, medical waste and pharmaceutical laboratories. Analysis of material compatibility with sterilization processes. Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Technical and validation service for clients (sterilizers, washer-disinfectors and sealers). Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment. Commercial activities and after sales service.

Marta Escudero

Regional Director, Europe

Issued by: LRQA Limited



Certificate Schedule

Location	Activities
Antonio Matachana, S.A. C/ Copérnic, 8, 08860 Castelldefels, Barcelona, Spain	ISO 9001:2015 Design, manufacture and final testing of sterilizers, disinfection and treatment equipment for medical devices, food, research, industry, medical waste and pharmaceutical laboratories. Analysis of material compatibility with sterilization processes. Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Technical and validation service for clients (sterilizers, washer-disinfectors and sealers). Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment.
Antonio Matachana, S.A. C/ Raurell 21-29 Nave 4, 08860 Castelldefels, Barcelona, Spain	ISO 9001:2015 Technical and validation service at customer's premises (sterilizers, washer-disinfectors and sealing machines).
Antonio Matachana, S.A. C/ Can Balmes, 1, 08460 Santa Maria de Palautordera, Barcelona, Spain	ISO 9001:2015 Manufacture of sterilization chambers, steam generators and other auxiliary vessels for use in sterilizers, as well as pressure vessels for use in effluent sterilization or thermal disinfection treatment equipment.
Antonio Matachana, S.A. C/ Raurell 21-29 Nave 1, 08860 Castelldefels, Barcelona, Spain	ISO 9001:2015 Distribution of equipment for communities, sterilization, surgical block, disinfection and morgue. Analysis of material compatibility with sterilization processes.
Matachana France, S.A. Europarc 5, Allée des Saules, 94043 Créteil Cedex, France	ISO 9001:2015 Commercial activities and after sales service.



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1297087-1

Certificate Holder: ANTONIO MATACHANA, S.A.
C/ Copèrnic 8
08860 Castelldefels, 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.: 92718020-90

Effective date: 2024-02-18

Expiry date: 2027-02-17

Issue date: 2024-02-16

Replaces certificate SX 1297087-1 issued 2023-07-13

This certificate can be validated on <https://www.certipedia.com>


Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate

Quality Management System EN ISO 13485:2016

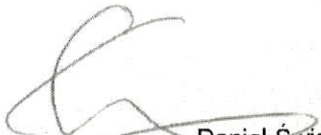
Registration No.: SX 1297087-1
Certificate Holder: ANTONIO MATACHANA, S.A.
C/ Copèrnic 8
08860 Castelldefels, Barcelona
Spain

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	ANTONIO MATACHANA, S.A. C/ Copèrnic 8 08860 Castelldefels, 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. Raurell 21-29, Nave 1 and 4 08860 Castelldefels, Barcelona Spain	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 process and for heat sealing processes of packaging for terminally sterilized devices.
/03	ANTONIO MATACHANA, S.A. Almogóvers 174 08018 Barcelona Spain	Distribution of equipment for sterilization and disinfection.
/04	ANTONIO MATACHANA, S.A. C/ Can Balmes 1 08460 Santa Maria de Palautordera, Barcelona Spain	Manufacture of sterilizer components.

Report No.: 92718020-90
Effective date: 2024-02-18
Expiry date: 2027-02-17
Issue date: 2024-02-16

This certificate can be validated on <https://www.certifiedia.com>


Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. 3.00.13062

Certificate Holder:

●●● matachana
ANTONIO MATACHANA, S.A.
Copèrnic 8
08860 Castelldefels (Barcelona)
Spain

Scope:

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

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity:

The certificate is valid from 2022-11-15 until 2025-11-14.
First certification 2013

www.tuv.com




TÜV Rheinland Ibérica Inspection,
Certification & Testing S.A.
Garrotxa, 10-12 – E-08820 El Prat de
Llobregat



TÜVRheinland®
Precisely Right.

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 1297087-1

Manufacturer: ANTONIO MATACHANA, S.A.
C/ Copèmic 8
08860 Castelldefels, Barcelona
Spain

EUDAMED Single
Registration No.: ES-MF-000018995

Products: Products of class IIa:

Z120113 CLEANING, DISINFECTION AND STERILISATION
INSTRUMENTS
D99 DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS
AND DETERGENTS FOR MEDICAL DEVICES – OTHER

Authorized representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-05-27
1	Scope extension for products class IIa D99	2024-07-12

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 92718020-90

Effective date: 2024-07-12

Expiry date: 2029-05-26

Issue date: 2024-07-12

This certificate can be validated on <https://www.certipedia.com>


Daniel Swiatko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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, SC500 series, models:

SC500V-1 SC500V-2 SC501V-1 SC501V-2 SC502V-1 SC502V-2
SC500E-1 SC500E-2 SC501E-1 SC501E-2 SC502E-1 SC502E-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 13445
EN 14222

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-B/B04902/12 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:

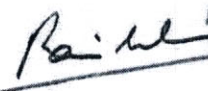
EN 61326-1

- 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, May 11th, 2021


Ramón Calvera Sagú
ANTONIO MATACHANA, S.A.
Director of Quality and of Research & Technology

ANTONIO MATACHANA, S.A.
c/ Almogàvers, 174
08018 - BARCELONA

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

