#### 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.
 92704673 020

 Effective date
 2023-07-13

 Expiry date
 2024-02-17

 Issue date
 2023-07-13

Replaces certificate SX 1297087-1 issued 2021-12-09

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 process 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.

Almogàvers 174 08018 Barcelona

Spain

Distribution of equipment for sterilization and disinfection.

 Report No.
 92704673 020

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

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#### 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:

/04 ANTONIO MATACHANA, S.A. Manufacture of sterilizer components.

C/Can Balmes 1 08460 Sta. María de Palautordera, Barcelona

Spain

 Report No.
 92704673 020

 Effective date
 2023-07-13

 Expiry date
 2024-02-17

 Issue date
 2023-07-13

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Daniel Świątko
TÜV Pheinland LGA Products GmbH
Tillystratse 2 · 90431 Nürnberg · Germany



