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

Daniel Światko TÜV Rheinland LGA Products GmbH

Tillystraße 2 · 90431 Nürnberg · Germany

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





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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. Almogívers 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.

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