

# 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: 2022-02-18

Expiry date: 2024-02-17

Issue date: 2021-12-09



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



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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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