

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60144134 0001

Report No.: 28300311 012

Manufacturer: ANTONIO MATACHANA, S.A.

Almogavers 174 08018 Barcelona

Spain

Products: Sterilizers, disinfection devices and sterilizing agents

(see attachment for products and sites included)

Replaces EC Certificate, Registration No.: HD 60100422 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-11-04

Date: 2019-11-04

Notified Body

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

HD 60144134 0001 28300311 012

Manufacturer:

ANTONIO MATACHANA, S.A. Almogavers 174 08018 Barcelona

Spain

Products:

Sterilizers:

- Sterilizer, Steam, Table Top Device
- Sterilizer, Steam, Large

Sterilizer and Disinfection Devices:

- Sterilizer, LTSF
- Sterilizer, HPO

Sterilizing Agent:

- LTSF-Sterilizing Solution
- HPO-Sterilizing Solution

Date: 2019-11-04

10/020 h 04.08 D TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Notified Body

Sebastian Mniszek



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.: HD 60144134 0001 Report No.: 28300311 012

Manufacturer:

ANTONIO MATACHANA, S.A. Almogavers 174 08018 Barcelona

Spain

Site included:

ANTONIO MATACHANA, S.A. Cop#rnic, 8, 08860 Castelldefels (BA), Spain

Activities:

Design/development and manufacture of sterilizers and disinfection devices

Date: 2019-11-04

10/020 h 04.08
TUV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Notified Body

Sebastian Mniszek