

**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.  
Almogàvers 174  
08018 Barcelona  
Spain

**Products:** Sterilizers, disinfection devices and sterilizing agents  
(see attachments for products included and sites)  
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.:** HD 60144134 0001  
**Report No.:** 28300311 012

**Organization:** ANTONIO MATACHANA, S.A.  
Almogàvers 174  
08018 Barcelona  
Spain

**Products:**

**Sterilizers:**

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

**Sterilizers and Disinfection Devices:**

- Sterilizer, LTSF
- Sterilizer, HPO

**Sterilizing Agent:**

- LTSF- Sterilizing Solution
- HPO-Sterilizing Solution

**Date: 2019-11-04**



**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

**Organization:** ANTONIO MATACHANA, S.A.  
Almogàvers 174  
08018 Barcelona  
Spain

Site included:

ANTONIO MATACHANA, S.A.  
Copèrnic, 8  
08860 Castelldefels (BA), Spain

Activities:

Design/ development and manufacture of sterilizers  
and disinfection devices

**Date: 2019-11-04**



**Notified Body**

  
**Sebastian Mniszek**