

EC CONFORMITY CERTIFICATE

The manufacturer Antonio Matachana, S.A., located at Carrer Almogàvers, 174, E-08018 Barcelona (Spain), CERTIFIES that the steam sterilizers Matachana brand, S1000(12) series, models:

1004V-1	1006V-1	1008V-1	1010V-1	1012V-1
1004V-2	1006V-2	1008V-2	1010V-2	1012V-2
1004E-1	1006E-1	1008E-1	1010E-1	1012E-1
1004E-2	1006E-2	1008E-2	1010E-2	1012E-2

being products within the scope of the European Directive 93/42/EEC concerning medical devices and classified to class IIb according to the rule 15 of the Annex IX, are in conformity with:

- Directive 93/42/EEC concerning medical devices, Annex I, according to the harmonized standard:

EN 285

- The more specific essential health and safety requirements of the Annex I of the Directive 2006/42/EC on machinery, according to the following harmonized standards:

EN ISO 12100

EN 60204-1

The conformity assessment according to Directive 93/42/EEC concerning medical, Annex II except II.4, with registration number HD 60100422 0001 from the European Notified Body TÜV Rheinland LGA Products GmbH located at Tillystrasse 2, D-90431 Nürnberg, allows to fix on each manufactured product, the CE0197 marking and to draw up the related EC conformity declaration.

- Directive 2014/68/EU concerning pressure equipment according to the following harmonized standards:

EN 14222

and German design code AD-2000:

AD 2000 Merkblatt

The conformity assessment according to Directive 2014/68/EU concerning pressure equipment, module B+C2 (EC type examination + conformity to type), with certificate number ATI/EP-B/B02609/09 from the European Notified Body Asistencia Técnica Industrial, S.A.E. (ATISAE) located in Avda. de la Industria 15 bis E-28760 Tres Cantos (Madrid), allows to fix on each manufactured product, the CE0053 marking and to draw up the related EC conformity declaration.

- Essential requirements set out in Annex I of the European Directive 2014/30/UE relating to electromagnetic compatibility according to the following standard:

EN 61326-1

- Principal elements on the safety objectives set out in Annex I of the European Directive 2014/35/UE relating to electrical equipment designed for use within certain voltage limits according to the following standards:

EN 61010-1

EN 61010-2-040

- Additionally, these products comply with the European Directive 2011/65/UE on restriction of the use of certain hazardous substances in electrical and electronic equipment.

Barcelona, January 2nd, 2019

Ramón Calvera Sagué

ANTONIO MATACHANA, S.A.

Director of Quality and of Research & Technology

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NOTE: For undated normative references, the latest edition of the referenced document (including any amendments) applies.