



CERTIFICATION

- CISA is certified according to UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 by the accredited body TUV Sud.
- CISA's steam sterilization autoclaves are manufactured according to the normative UNI 285:2016.
- CISA's washing and disinfection machines and CISA's endoscopes reprocessing machines are manufactured according to the normative EN ISO 15883.
- CISA's Quality Management System and products are certified according to the Pressure Equipments Directive 2014/68/EU (ex 97/23/EC) about the design and the manufacture of those components.

DISINFECTOR

CONFORMITY TO THE DIRECTIVE FOLLOWINGS AND LAWS (and following changes)
European directive 93/42/EEC of 1993/06/14 related to the Medical Devices
2007/47/EC (Annex II) related to the Medical Devices;
Machinery directive 2006/42/EC; Electromagnetic Compatibility Directive:
2014/30/EU : Low Voltage Directive: 2014/35/EU

CONFORMITY TO THE FOLLOWING NORMS OF PRODUCT

The normative harmonize (published in the O.J. of the European Community)
applicable to this product are:

**CEI EN 61010-1, CEI EN 61010-2-040, CEI EN 60204-1,
EN 61326-1, UNI EN ISO 15883-1, UNI EN ISO 15883-2, ISO 15883-6**

PRODUCT REALIZED WITH SYSTEM OF QUALITY

UNI EN ISO 9001:2015, UNI CEI EN ISO 13485:2016

**Notified body: TÜV Product Service GmbH, Ridlerstr.65,80339 München, Germany.
Certified: G1 086788 0007 n° Notified Corporate body 0123**

STERILIZER

CONFORMITY TO THE DIRECTIVE FOLLOWINGS AND LAWS (and following changes)
European directive 93/42/EEC of 1993/06/14 related to the Medical Devices;
2007/47/EC (Annex II) related to the Medical Devices; Pressure Equipment Directive
2014/68/UE; EN 13445 current edition; Machinery directive 2006/42/EC;
Electromagnetic;

Compatibility Directive:

2014/30/UE; Low Voltage Directive: 2014/35/UE

CONFORMITY TO THE FOLLOWING NORMS OF PRODUCT

The normative harmonize (published in the O.J. of the European Community)
applicable to this product are:

CEI EN 61010-1:2013, CEI EN 61010-2 040:2015, CEI EN 60204-1:2016, EN 61326-1:2013, UNI EN 285:2016

PRODUCT REALIZED WITH SYSTEM OF QUALITY

UNI EN ISO9001:2015, UNI CEI EN ISO13485:2016

ENDOSCOPY

CONFORMITY TO THE FOLLOWING NORMS OF PRODUCT

The normative harmonize (published in the O.J. of the European Community)
applicable to this product are:

**CEI EN 61010-1:2010/A1:2019, CEI EN 61010-2-040:2015, CEI EN 60204-1:2016,
EN 61326-1:2013, UNI EN ISO 15883-1:2014, UNI EN ISO 15883-4:2019**