



## DECLARATION OF CONFORMITY EC

Manufacturer: **CISA Production S.r.l.**  
Address: **Mugnano –LUCCA- Italy**

Products: **Steam Sterilizer**  
Model: **P-640H**  
Valid for S/N: **SN00000**

Made in the productive site of: **Via E. Mattei, snc – 55100 Mugnano (LU)**

Classification (Annex IX Directive 93/42/EEC): **IIB** rule **15**

We herewith declare under our sole responsibility that the product above mentioned described in the Technical File **P-640H** current revision to which the declaration refers, is conforming to the essential requisite of the Directive European Medical Devices 93/42/EEC and 2007/47/EC and to the applicable standards.

The whole documentation of support is preserved near the our center and to disposition of the competent Authorities and the Notified body.

The CISA Production has developed a procedure for the overseeing post-sale of such Medical Device in accord to the MEDDEV 2.12/1.

### 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 ISO 17665-1:2007, UNI EN 285:2016**

### 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**

Place, Dates: **Lucca 05 – 10 – 2020**

Signature  
Name  
Position

  
**Francesco Crotti**  
**Technical Director**