

Certificate of Compliance



No. 0H170309.JBMCY04

Technical Construction File no. TEJS17021610154 ,TLJS17021610155

Certificate's
Holder:

HEFEI SADA MEDICAL EQUIPMENT
CO., LTD

No. 1412 Jingdian Plaza, Fanhua Avenue, EDZ,
Hefei, Anhui, China.

Certification ECM
Mark:



Product:
Model(s):

STERILIZER

VA-SV, VA-SA, VA-SD, VA-FD, VA-SJ, VA-FJ,
TS-A, TS-AD, TS-AJ, TS-B, TS-C, TS-CD, TS-DDV
HA-BC, HA-BA, HA-BB, HA-BD, HA-BV, WG-HV
WG-HN, HA-BVD, HA-BVS, SD-D, SD-H

Verification to:

Standard:

EN 13060:2014, EN 61010-1: 2010, EN 61010-
2-040: 2015, EN 60601-1-2:2015, EN 61000-3-
2:2014, EN 61000-3-3:2013, EN ISO 14971:2012

related to CE Directive(s):

Directive 93/42/EEC including 2007/47/EC (Medical
Devices)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the **CE** Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

Date of issue 23 December 2016

Expiry date 22 December 2021

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ECM