

# VERIFICATION



No. 3N230831.BDQW46

Verification's Holder: Biobase Disinfection (Shandong) Co., Ltd.  
Room 303, R&D Building, OLABO Intelligent Manufacturing Industrial Park, No. 1, Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China

Verification ECM Mark:



Product: Table Top Autoclave, Vertical Autoclave, Hand Wheel Vertical Autoclave, Horizontal Autoclave, Large Horizontal Autoclave, Cassette Sterilizer, Portable Autoclave

Model(s): BKM-Series, BKQ-Series, BKS-Series

Verification to: Standard:  
EN 13445-1:2021, EN 13445-2:2021+A1:2023,  
EN 13445-3:2021, EN 13445-4:2021+A1:2023,  
EN 13445-5:2021

related to CE Directive(s):  
2014/68/EU (Pressure Equipment) Category II Module D1

**This document has been issued in accordance with the European Commission's note of 14 September 2022 ref. Ares (2022) 6342894 concerning voluntary certifications with non-notified procedure and for products intended for third countries outside the EU market.**

The manufacturer has voluntarily decided to submit its documents concerning the above-mentioned product for verification. Ente Certificazione Macchine confirms that the documentation made available and immediately returned to it, as containing sensitive data, meets the essential requirements of the above-mentioned directives. The verification activity carried out exclusively concerned the technical documentation and no verification was carried out on the product. This document cannot replace the EC Declaration of Conformity. The above conformity mark can be affixed to the technical documentation in accordance with the ECM regulation on its issue and use, published on the website [www.entecerma.it](http://www.entecerma.it)

**Issuance date: 31 August 2023**

**Expiry date: 30 August 2028**

For online check:



Approver  
Ente Certificazione Macchine  
Legal Representative  
Luca Bedonni



Ente Certificazione Macchine Srl

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# POSI

## CERTIFICATE

This is to certify that the Quality Management System of  
**Biobase Disinfection (Shandong) Co., Ltd.**

Business License Number: 91370181MA3C1M6N5G  
Registered Address: Room 303, R&D Building, OLABO Intelligent Manufacturing Industrial Park,  
No. 1 Biobase Road, Ancheng Town, Pingyin County, Jinan City, Shandong Province, China  
Audit Address: Workshop 11, Jidong Smart Manufacturing New Town, 2666 Puxue Road,  
Zhangqiu District, Jinan City, Shandong Province, China

applicable to

Production and sales of Vertical Autoclave, Table Top Autoclave,  
Horizontal Autoclave, Large Horizontal Autoclave, Portable Autoclave

has been assessed and registered by POSI against the provisions of

**GB/T 42061-2022/ISO 13485:2016**

This registration is subject to the company maintaining a Quality Management System,  
to the above standard, which will be monitored by POSI.  
Certified organization shall accept regular surveillance audit, the validity of certificates shall be  
maintained for the positive result of audit.

Please consult the website: [www.posicert.com](http://www.posicert.com)

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



A handwritten signature in black ink, appearing to read 'Jie Shen'.

General Manager

Certificate Registration No: 381220111R0M  
Initial issue date: 2022.08.08 Issue date: 2024.08.06 Valid until: 2025.08.07

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: [info@posicert.com](mailto:info@posicert.com)

