



# Certificate of Compliance

No. 4Q200328R.ZBB0078

Certificate's  
Holder:

ZHEJIANG BAOJIA BIOTECHNOLOGY  
CO.,LTD  
NO 43 SUHUA STREET SUXI TOWN YIWU CITY  
ZHEJIANG PROVINCE CHINA

Certification ECM  
Mark:



Product:  
Model(s):  
Verification to:

Disposable Face Mask 17.5\*9.5  
Protective Mask KN95  
Standard:  
EN 149: 2001 + A1 2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

**Issuance date: 28 March 2020**

**Expiry date: 27 March 2025**

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni

**Ente Certificazione Macchine Srl**

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3/30/2020

# FDA | U.S. Food and Drug Administration



## Registration Confirmation

Facility: ZHEJIANG BAOJIA BIOTECHNOLOGY CO.,LTD, Yiwu, Zhejiang, CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

**As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.**

**You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.**

**Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.**

**Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.**

**Should you have any questions, please send an e-mail to [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) (<mailto:reglist@cdrh.fda.gov>).**

**The Owner/Operator Number for this Registration is: 10065771**

### Facility Information

Initial Importer:	N
Facility Name:	ZHEJIANG BAOJIA BIOTECHNOLOGY CO.,LTD
Address:	No. 43 Suhua Street Suxi Town Yiwu, Zhejiang, 322000, CHINA
Foreign Trade Zone:	N
Facility URL:	<a href="https://boysunjun.1688.com/">https://boysunjun.1688.com/</a>

**Owner/Operator Information**

**Owner/Operator Number:** 10065771  
**Contact Name:** Lingyu Chen  
**Company:** ZHEJIANG BAOJIA BIOTECHNOLOGY CO.,LTD  
**Address:** No. 43 Suhua Street Suxi Town  
Yiwu, ZHEJIANG, 322000, CHINA  
**Telephone:** 86 - 0579 - 85413899  
**Fax:** 86 - 579 - 85527756  
**E-mail:** baojia@sj-china.com

**Official Correspondent Information**

**Contact Name:** David Lennarz  
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**DUNS Number:** 139242874

**United States Agent Information**

**Contact Name:** David Lennarz  
**Contact Title:** Mr  
**Business Name:** Registrar Corp  
**Address:** 144 Research Drive  
Hampton, Virginia, 23666, UNITED STATES  
**Phone:** 757 - 2240177  
**Fax:** 757 -2240179  
**DUNS Number:** 139242874  
**E-mail:** david.lennarz@registrarcorp.com

**Device Listings**

<b>Listing Number</b>	<b>Premarket Submission Number/Type</b>	<b>Product Code(s)</b>	<b>Device Name(s)</b>	<b>Activities</b>	<b>Importers</b>
D382293	Enforcement Discretion	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance	Manufacturer	

**Date of Initial Registration: Mon Mar 30 15:49:40 EDT 2020**