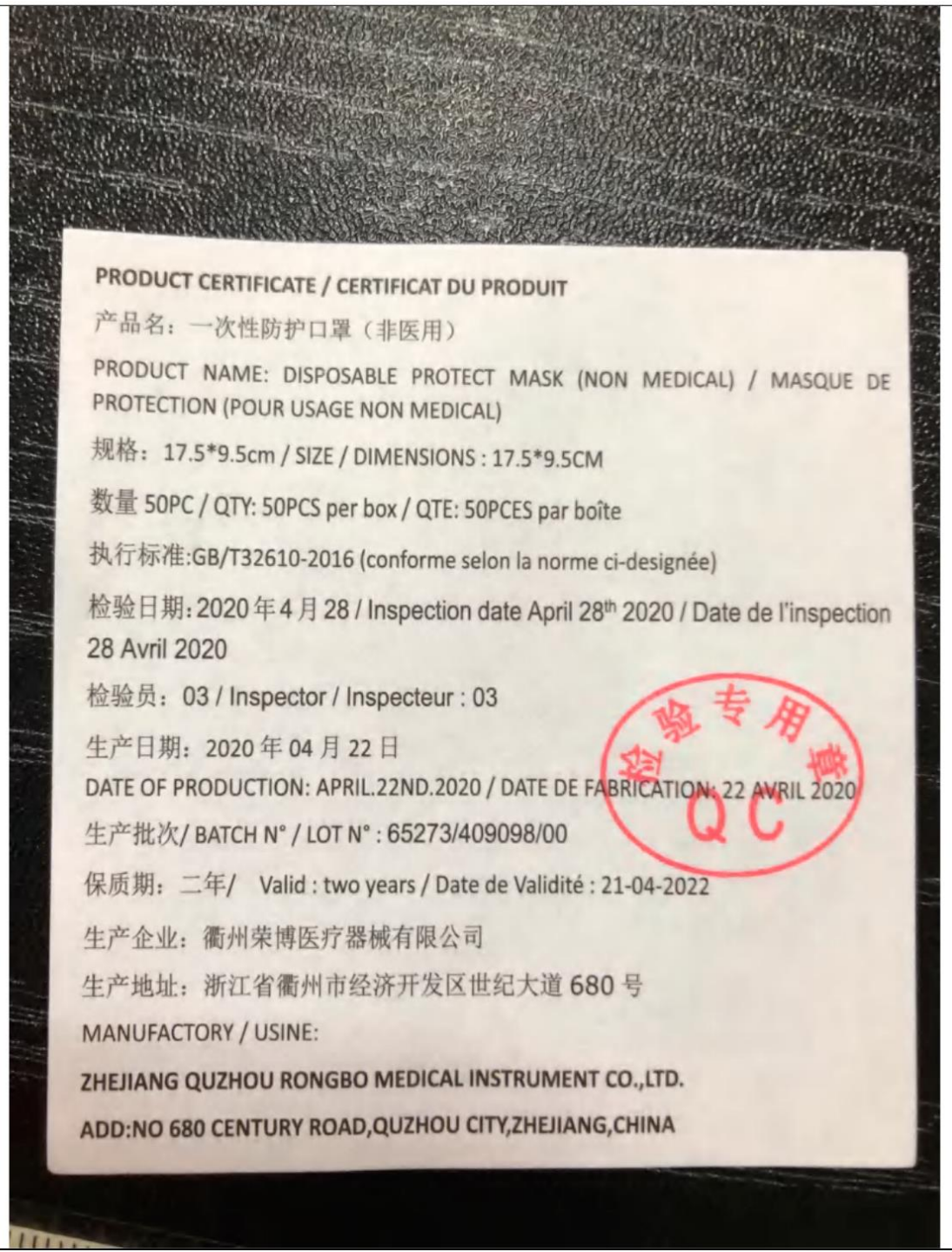


合格证 Product Certificate



PRODUCT CERTIFICATE / CERTIFICAT DU PRODUIT

产品名：一次性防护口罩（非医用）

PRODUCT NAME: DISPOSABLE PROTECT MASK (NON MEDICAL) / MASQUE DE PROTECTION (POUR USAGE NON MEDICAL)

规格：17.5*9.5cm / SIZE / DIMENSIONS : 17.5*9.5CM

数量 50PC / QTY: 50PCS per box / QTE: 50PCES par boîte

执行标准:GB/T32610-2016 (conforme selon la norme ci-designée)

检验日期:2020年4月28 / Inspection date April 28th 2020 / Date de l'inspection 28 Avril 2020

检验员: 03 / Inspector / Inspecteur : 03

生产日期: 2020年04月22日

DATE OF PRODUCTION: APRIL.22ND.2020 / DATE DE FABRICATION: 22 AVRIL 2020

生产批次/ BATCH N° / LOT N° : 65273/409098/00

保质期: 二年/ Valid : two years / Date de Validité : 21-04-2022

生产企业: 衢州荣博医疗器械有限公司

生产地址: 浙江省衢州市经济开发区世纪大道 680 号

MANUFACTORY / USINE:

ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO.,LTD.

ADD:NO 680 CENTURY ROAD,QUZHOU CITY,ZHEJIANG,CHINA



检测报告 Test Report



检测报告 Test report

检验报告 TEST REPORT

浙江省轻工业产品质量检验研究院
Zhejiang Light Industrial Products Inspection and Research Institute
国家轻工业产品质量监督检验中心(浙江)
National Light Industrial Quality Supervision Inspection Center (Zhejiang)

检验报告

检测项目	检测标准	检测结果	判定
透气性	GB/T 19082-2009	≥ 1.0	合格
阻燃性	GB/T 19082-2009	≤ 1.0	合格
静电性能	GB/T 19082-2009	≤ 1.0	合格

检验报告

序号	检测项目	检测标准	检测结果	判定
1	透气性	GB/T 19082-2009	≥ 1.0	合格
2	阻燃性	GB/T 19082-2009	≤ 1.0	合格
3	静电性能	GB/T 19082-2009	≤ 1.0	合格



3/27/2020

FDA | U.S. Food and Drug Administration



Registration Confirmation

Facility: ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO., LTD., Quzhou City, 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).

The Owner/Operator Number for this Registration is: 10065054

Facility Information

Initial Importer:	N
Facility Name:	ZHEJIANG QUZHOU RONGBO MEDICAL INSTRUMENT CO., LTD.
Address:	No.680 Century Avenue Quzhou City, Zhejiang, 324000, CHINA
Foreign Trade Zone:	N



Manufacturer's name:	Zhejiang Quzhou Rongbo Medical Instrument Co.,Ltd.
Address:	No680 Century Road Quzhou City, Zhejiang Province, China
Date:	15.05.2020
CCQS Project Reference:	CE-PC-200511-364

Confirmation Letter

To whom it may concern:

This is to confirm that **Zhejiang Quzhou Rongbo Medical Instrument Co.,Ltd.** Address: **No680 Century Road Quzhou City, Zhejiang Province, China** has entered into the service agreement **CE-PC-200511-364** with CCQS Certification Services Limited, with regards to the application of Module B EU Type Examination Certification and Module D Production Monitoring for **Particle filtering half mask, Model: RB-008** within the scope of Personal Protective Equipment Regulation(EU)2016/425 Category III.

Please note this document does not provide the function of a EU Type Examination Certificate. This document merely confirms that the project referenced above is currently under our assessment.

If in any doubt about the integrity of this letter, please contact CCQS by email to verify.

Yours Faithfully,



CCQS Certification Services Limited
Block 1, Blanchardstown Corporate Park, Ballycoolin Rd.,
Blanchardstown, Dublin 15, D15 AKK 1 Ireland
Tel: +353(0)1 588 6920
Email info@ccqs.ie
Registered in Ireland as a Limited Company No. 623897

Approved by
Ireland Government
as a Notified Body for
CE Marking No. 2834