Certificate

No. ICR Polska/M8403020

CE

Name and address of certificate owner: Jiangxi Kangmeijie Hygiene Materials Co.,Ltd No.688 Lianfu Avenue, Changleng Industry Zone, Xinjian District, Nanchang City, Jiangxi Province, PRC

Name and address of manufacturer: Jiangxi Kangmeijie Hygiene Materials Co.,Ltd No.688 Lianfu Avenue, Changleng Industry Zone, Xinjian District, Nanchang City, Jiangxi Province, PRC

Product name: Disposable Face Mask

Product types: FM01,FM02,FM03,FM04,FM05,FM06,FM07,FM08,FM09

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-02. Evaluation has been carried out in accordance with test reports made by EUROPEAN QUALITY TEST CO., LTD.

No. of test reports: KMJ-2020-0314

Certificate issue date: 18.03.2020

Expiration date: 17.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8430.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director: Rafał Kalinowski

Warsaw, 18. 03. 2020

ICR Polska Co. Ltd

ul. Plac Przymierza 6, 03-944 Warszawa

www.icrpolska.com, e-mail: icrpolska@icrcpa.com

International Certification Registrar · International Certification Registrar · International Certification Registrar

intertek
Total Quality Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

MEDICAL CO., LTD.

Main Site: Jiangsu Province, China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Manufacture and distribution of disposable plastic medical equipment covers, non-woven drapes, Urine Collection bag, wound bed preparation tool, disposable plastic medical products such as fluid management system connectors, valves, spike, roller clamp, hand brush, inhalers, blood smear applicator, type safe segment piercing device, blood transfer straw, urine transfer straw, urine tube and cap, negative suction system.

Certificate Number: 0085778

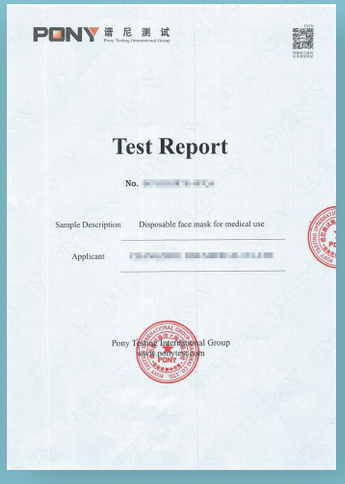
Initial Certification Date: 15 July 2011

Certificate Issue Date: 04 January 2018

Certificate Expiry Date: 14 July 2020

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd., 1829, 32nd avenue, Lachine, QC, H8T 3J1, Canada



PONY 谱尼测试 Pony Testing International Group

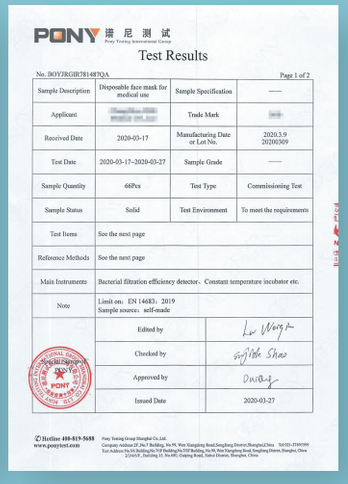
Test Report

No.

Sample Description: Disposable face mask for medical use

Applicant

Pony Testing International Group
www.ponytest.com



PONY 谱尼测试 Pony Testing International Group

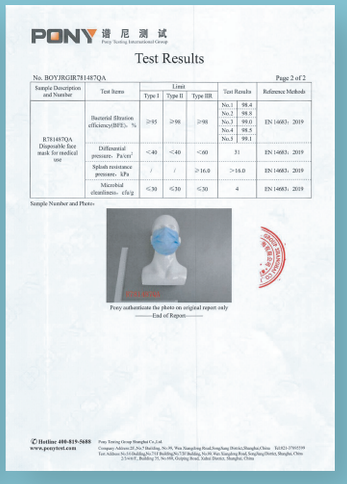
Test Results

No. BOY/RGIR781487QA Page 1 of 2

Sample Description	Disposable face mask for medical use	Sample Specification	——
Applicant		Trade Mark	——
Received Date	2020-03-17	Manufacturing Date or Lot No.	2020.3.9 20200309
Test Date	2020-03-17~2020-03-27	Sample Grade	——
Sample Quantity	66Pcs	Test Type	Commissioning Test
Sample Status	Solid	Test Environment	To meet the requirements
Test Items	See the next page		
Reference Methods	See the next page		
Main Instruments	Bacterial filtration efficiency detector、Constant temperature incubator etc.		
Note	Limit on：EN 14683：2019 Sample source：self-made		
	Edited by	Liu Wenjia	
	Checked by	Sun Yibo Shao	
	Approved by	Dai Qing	
	Issued Date	2020-03-27	

Hotline 400-819-5688
www.ponytest.com

Pony Testing Group Shanghai Co.,Ltd.
Company Address:2F,3#,7 Building, No.99, Wen Xiangdong Road,Songjiang District,Shanghai,China Tel:021-37695599
Test Address:No.5#,Building,7#,TCF Building,No.99, Wen Xiangdong Road,Songjiang District,Shanghai, China
2/3/4/F., Building 21, No.600, Guiping Road, Xuhui District, Shanghai, China



PONY 谱尼测试 Pony Testing International Group

Test Results

No. BOY/RGIR781487QA Page 2 of 2

Sample Description and Number	Test Items	Limit Type I	Limit Type II	Limit Type IIR	Test Results	Reference Methods
BY/RGIR781487QA Disposable face mask for medical use	Bacterial filtration efficiency(BFE)，%	≥95	≥98	≥98	No.1 98.4 No.2 98.8 No.3 99.0 No.4 98.5 No.5 99.1	EN 14683：2019
	Differential pressure，Pa/cm²	<40	<40	<60	31	EN 14683：2019
	Splash resistance pressure，kPa	/	/	≥16.0	>16.0	EN 14683：2019
	Microbial cleanliness，cfu/g	≤30	≤30	≤30	4	EN 14683：2019

Sample Number and Photo:

Pony authenticate the photo on original report only

End of Report

Hotline 400-819-5688
www.ponytest.com

Pony Testing Group Shanghai Co.,Ltd.
Company Address:2F,3#,7 Building, No.99, Wen Xiangdong Road,Songjiang District,Shanghai,China Tel:021-37695599
Test Address:No.5#,Building,7#,TCF Building,No.99, Wen Xiangdong Road,Songjiang District,Shanghai, China
2/3/4/F., Building 21, No.600, Guiping Road, Xuhui District, Shanghai, China