3. 💰 ***n95口罩***

国内版（kn95）：GB2626-2006

外贸版（n95）：可做欧盟标准FFP2和FFP3两种规格

kn95材料

外层：50g厚度无纺布

中层：50g厚度95熔喷布

内层：50g厚度亲肤无纺棉

EN 14683标准
医用KN95


卡迪生物
N95 防护口罩
细菌过滤效果>95%
人体工学设计
10 PCS
PM2.5

中文包装


KADI BIOLOGICAL
N95 PROTECTIVE MASK
Bacterial filtration effect >95%
Three level filtering
Safety and health
Skin care fabric
10 PCS
CLASS II MEDICAL DEVICES

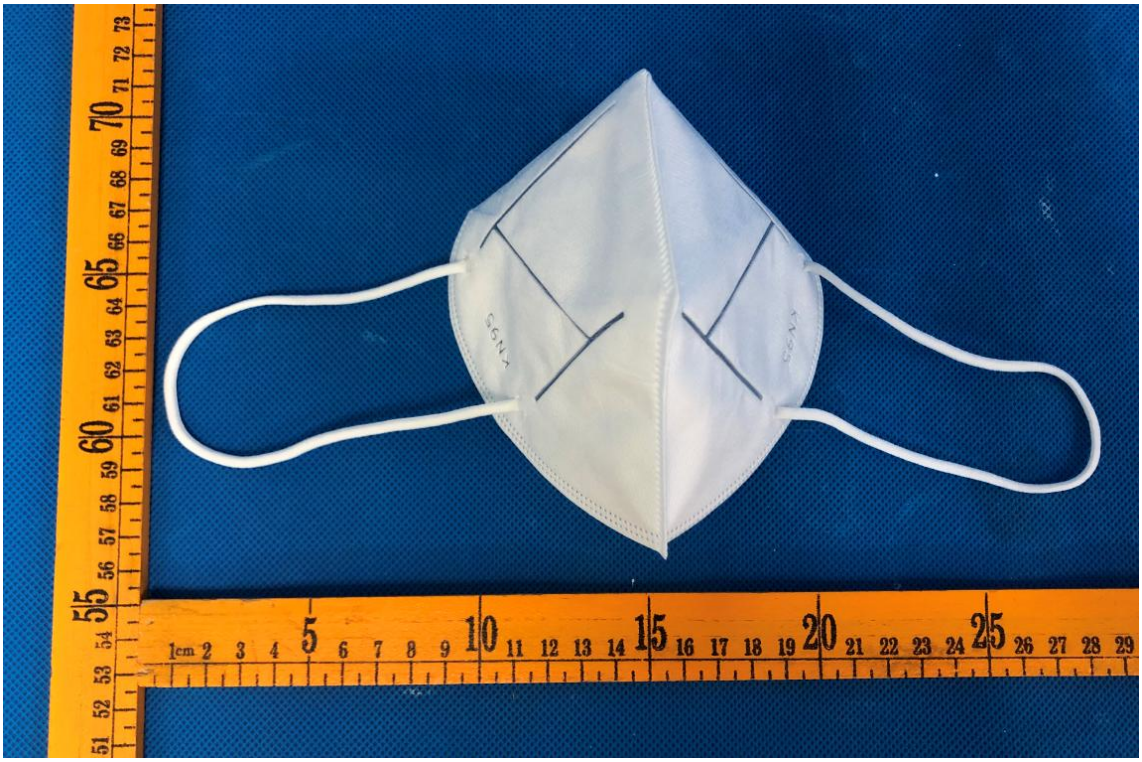
英文包装

Photos document

General view for Y-001

General view for Y-001

Photos document



General view for Y-001

General view for Y-001

===End of the report===

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD

Add: 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd.,Feidong Economic Development Zone,231600,Hefei,Anhui,China

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

The Owner/ Operator Number for this Registration is :10062933

Listing No	Code	Premarket Submission NO.	Device Name
D374892	**KHA**		**Medical Surgical Mask, Medical Protective Mask; Mask, Face Mask, Nonwoven Face Mask, Disposable Medical face Mask**
D374893	**MSH**		**N95 Protective Mask**

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate‐holder's device or establishment by the U.S Food and Drug Administration.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification:Mar. 11, 2020

Date of expiration:Dec. 31, 2020

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

36 Soyth 18th Avenue, Suite A Brighton,CO USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

Verification of CE Registration

Certificate No.: CE20200309

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

Manufacturer: HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD
No.3Building, Prospect Science Park, Xincheng Development Zone,231600, Feidong County, Hefei,,China

EC-Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

On its product as follows:

Product name: Disposable medical mask, medical surgical mask, medical protective mask，Face Mask，disposable face mask

Classification: Class I.

No Non-compliance according to the requirements of the Medical Device Regulation (EU) 2017/745 Annex II and Annex III was detected, and the aforementioned device complies with the Regulation including all General Safety and Performance Requirements defined in Annex I.

The manufacturer has provided the EU Declaration of Conformity according to the Medical Device Regulation (EU) 2017/745 - article 19 requirements, confirming that this medical device, as stipulated above, is fulfilling the applicable requirements of the Medical Device Regulation (EU) 2017/745.

The notification of aforementioned device has been completed by the European Representative in Germany. The German Competent Authority is notified of the manufacturer's medical devices and has allocated registration.

Issue Date:Mar.09,2020
Date of expiry:Mar.08,2025

Justin

SIGNATURE

CE

ABMED SERVICE INC.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
E-mail:info@abmed.com.cn

TEST REPORT

EN 14683:2005

Surgical masks - Requirements and test methods

EN ISO 10993-1:2009+AC:2010

Biological evaluation of medical devices –

Part 1: Evaluation and testing within a risk management process

Report Reference No..... :	BET20200213017MDD
Tested by (name + signature)..... :	Man Li
Approved by (name + signature) . :	Dexter Chan
Date of issue..... :	2020-03-19
Total number of pages..... :	15
Testing Laboratory..... :	Guangzhou Betek Testing Services Co., Ltd
Address..... :	No. 106, Fengze East Road, Nansha District, Guangzhou City, Guangdong Province, P.R. China.
Applicant's name..... :	HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD
Address..... :	2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd.,Feidong Economic Development Zone, Hefei, Anhui, China
Test specification:	
Standard..... :	EN 14683:2005 EN ISO 10993-1:2009+AC:2010
Test procedure ..... :	CE-MDD
Non-standard test method……..:	N/A
Test Report Form No..... :	EN 14683_B
Master TRF..... :	Dated 2014-09
Trade Mark..... :	None
Manufacturer ..... :	HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd.,Feidong Economic Development Zone, Hefei, Anhui, China
Test item description ..... :	KN95 Medical Face Mask
Model/Type reference ..... :	Y-001

Possible test case verdicts:	
- test case does not apply to the test object..... :	N/A
- test object does meet the requirement ..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing..... :	
Date of receipt of test item..... :	2020-02-13
Date (s) of performance of tests ..... :	2020-02-13 to 2020-03-19

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

General product information:

1. This product, named Medical Face Mask, for medical and similar used.

Classification..... : ☐ Type I ☐ Type II ☒ Type IIR

List of Attachments (including a total number of pages in each attachment):

This report has total 15 numbers, include annex I.

Annex I: Photos document, 2 pages.

Summary of testing: tests performed (name of test and test clause)

The tested samples comply with the requirements of EN 14683:2005 and EN ISO 10993-1:2009+AC:2010.

Summary of compliance with National Differences

National differences for Europe groups were taken into account.

Copy of marking plate

KN95 Medical Face Mask

Trade Mark: KADI

Model: Y-001

EN 14683:2005

EN ISO 10993-1:2009+AC:2010

Type IIR

CE

Manufacturer: HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO.,LTD

Address: 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd.,Feidong Economic Development Zone, Hefei, Anhui, China

Note:

- The Markings are attached on external enclosure and visible during normal use.
- The height of CE mark should be minimum 5,0mm.
- The importer name and address were marked on the product.

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		—
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	Type II	P
5	**Requirements**		—
5.1	General		P
5.1.1	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.		P
	The medical face mask shall not disintegrate, split or tear during intended use.		P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).		P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
5.2	Performance requirements		P
5.2.1	General		P
	All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.		P
5.2.2	Bacterial filtration efficiency (BFE)		P
	When tested in accordance with Annex B		P
	the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.		P
5.2.3	Breathability		P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.		P
5.2.4	Splash resistance		P
	When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		P
5.2.5	Microbial cleanliness (Bioburden)		P
	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ⩽ 30 cfu/g tested (see Table 1).		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:		P
	The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.		P
	Weigh each mask prior testing.		P
	The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).		
	The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.		P
	After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µ filter and laid down on a TSA plate for the total viable aerobic microbial count.		P
	Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration.		P
	The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.		P
	The total bioburden is expressed by addition of the TSA and SDA counts.		P
	In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.		P
5.2.6	Biocompatibility		P
	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact.		P
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime.		P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		P
	The test results shall be available upon request.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
5.2.7	Summary of performance requirements		P
6	**Labelling and information to be supplied**		—
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to		P

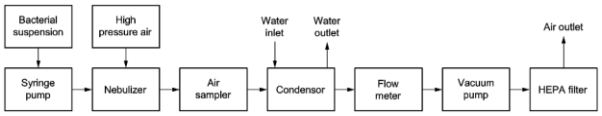
EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	be specifiedon the packaging in which the medical face mask is supplied.		
	The following information shall be supplied in addition:		P
	a) number of this European Standard;		P
	b) type of mask (as indicated in Table 1).	Type IIR	P
	EN ISO 15223-1 and EN 1041 should be considered.		P
Annex A	**(informative) Information for users**		—
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose.		P
	The majority of the nuclei are between 0,5 μ m and 12 μ m in diameter and especially the larger droplets can contain micro-organisms from the source site.		P
	Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
	The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment.		P
	This standard describes two types of medical face masks with associated protection levels.		P
	As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations.		P
	Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.		P
	A special case, also covered by the European Medical Devices legislation, is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids and particles that are created in the surgical environment, e.g. by the use of electro-cautery devices.		N/A
	If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered.		N/A
	Performance requirements for respirators are the scope of EN 149.		N/A
	The filtration capacity of mask materials can vary depending on the filter media.		P
	The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose.		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.		P
	The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations.		P
	It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made.		P
	It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen.		P
	Users should request such information from their suppliers.		P
	A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time.		P
	The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.		P
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.		P
	When there is a further need for protection then a new mask should be put on.		P
	Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.		P
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		P
	Masks with very different performance are, however, available.		P
	Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.		P
Annex B	**(normative) Method for in-vitro determination of bacterial filtration efficiency (BFE)**		—
	WARNING — Staphylococcus aureus is a pathogen.		P
	The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P
	An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	mask material and the impactor under vacuum.		
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.		P
B.2	Reagents and materials		P
B.2.1	General		P
	B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.		P
B.2.2	Tryptic soy agar		P
	Formula/liter:		P
	Enzymatic digest of casein 15 g		P
	Enzymatic digest of soybean meal 5 g		P
	Sodium chloride 5 g		P
	Agar 15 g		P
	Final pH 7,3 ± 0,2 at 25 °C		P
B.2.3	Tryptic soy broth		P
	Formula/liter		P
	Enzymatic digest of casein 17 g		P
	Enzymatic digest of soybean meal 3 g		P
	Sodium chloride 5 g		P
	Dipotassium phosphate 2,5 g		P
	Dextrose 2,5 g		P
	Final pH 7,3 ± 0,2 at 25 °C		P
B.2.4	Peptone water		P
	Formula/liter		P
	Peptone 10 g		P
	Sodium chloride 5 g		P
	Final pH 7,2 ± 0,2 at 25 °C		P
B.2.5	Culture of Staphylococcus aureus ATCC 6538, growing on tryptic soy agar slants		P
B.3	Apparatus		P
B3.1	Six stage cascade impactor		P
B.3.2	Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) μ m when in contact with		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	the impactor		
B.3.3	Aerosol chamber, glass, 600 mm long and 80 mm in external diameter		P
B.3.4	Flow meters, capable of measuring a flow rate of 28,3 l/min		P
B.3.5	Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa		P
B.3.6	Erlenmeyer flasks, 250 ml and 500 ml capacity		P
B.3.7	Peristaltic or syringe pump, capable of delivering 0,01 ml/min		P
B.3.8	Vacuum pump, capable of maintaining a flow rate of 57 l/min		P
B.4	Test specimens		P
	Test specimens shall be cut from complete masks.		P
	Each specimen shall be minimum 100 mm by 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask.		P
	The number of specimens that shall be tested is minimum 5 (five), but can be greater and shall be increased if necessary to allow for an AQL of 4 %.		P
	All specimens tested shall be taken from representative areas to incorporate all/any variation in construction.		P
	Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.		P
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		P
B.5	Preparation of bacterial challenge		P
	Staphylococcus aureus (see B.2.4) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h.		P
	The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 105 cfu/ml.		P
	The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test.		P
	The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly.		P
	The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) μ m (see B.6.9).		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
B.6	Procedure		P
B.6.1	Assemble the apparatus in accordance with the flow chart shown in Figure B.1.		P
B.6.2	Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.		P
B.6.3	Perform a positive control run without a test specimen.		P
	Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min.		P
	Deliver the bacterial challenge for 1 min.		P
	Maintain the airflow through the impactor for 2 min.		P
	Then remove the plates from the impactor.		P
	Ensure that each plate is numbered to indicate its position in the impactor.		
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.6.5	Repeat this procedure for each test specimen.		P
B.6.6	After the last test specimen has been tested, perform a further positive control run.		P
B.6.7	Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.		P
B.6.8	Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.		P
B.6.9	For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the “positive hole” conversion table1) in accordance with the instructions of the cascade impactor manufacturer (stages 3 to 6).		P
	For the two positive control runs, take the mean of the two totals.		P
	From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the “positive hole” conversion table in accordance with the instructions of the cascade impactor manufacturer.		P
B.7	Calculation of bacterial filtration efficiency		P
	For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:		P
	$B = (C - T) / C \times 100$		P
	Where C is the mean of the total plate counts for the two positive control runs;		P
	T is the total plate count for the test specimen.		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
B.8	Test report		P
	The following information shall be given in the test report;		P
	a) number and date of this European Standard;		P
	b) lot number or batch code of the masks tested;		P
	c) dimensions of the test specimens and the size of the area tested;		P
	d) which side of the test specimen was facing towards the challenge aerosol;		P
	1) See the positive hole conversion table found in the Andersen sampler user manual.		P
	e) flow rate during testing;		P
	f) mean of the total plate counts of the two positive controls;		P
	g) mean plate count of the negative controls;		P
	h) bacterial filtration efficiency for each test specimen.		P
			P
Annex C	**(normative) Method for determination of breathability (differential pressure)**		—
C.1	Principle		P
	A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1. Water-filled manometers (M1 and M2) are used to measure the differential pressure.		P
	A flow meter is used for measurement of the airflow.		P
	An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.		P
C.2	Apparatus		P
C.2.1	Flow meter, capable of measuring an airflow of 8 l/min		P
C.2.2	Manometers, M1 and M2 or differential manometer		P
C.2.3	Electric vacuum pump		P
C.2.4	Valve		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
C.3	Test specimens		P
	Test specimens are complete masks or shall be cut from masks.		P
	Each specimen shall be able to provide 5 different circular test areas of 2,5 cm in diameter.		P
	If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire mask.		P
	The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %.		P
	All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction.		P
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		P
C.4	Procedure		P
C.4.1	The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.		P
C.4.2	The pump is started and the flow of air adjusted to 8 l/min.		P
C.4.3	The manometers M1 and M2 are read and recorded.		P
C.4.4	The procedure described in steps C.4.1 through C.4.3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.		P
C.5	For each test specimen calculate the differential pressure Δ P as follows:		P
	Δ P = (Xm1 – Xm2)/4,9		P
	where Xm1 is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;		P
	Xm2 is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;		P
	4,9 is the cm2 area of the test material;		P
	Δ P is the differential pressure per cm2 of test material expressed in Pa.		P
C.6	Test report		P
	The following information shall be given in the test report:		P
	a) number and date of this European Standard;		P

EN 14683:2005 EN ISO 10993-1:2009+AC:2010			
Clause	Requirement + Test	Result - Remark	Verdict
	b) lot number or batch code of the masks tested;		P
	c) flow rate during testing;		P
	d) differential pressure for each test specimen.		P
Annex ZA	**(informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices**		—
	This European Standard has been prepared under a mandate given to CEN by the European Commission Union to provide a means of conforming to the essential requirements of New Approach EU Directive 93/42/EEC concerning medical devices.		P
	Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.		P

统一社会信用代码
91340122322749708(1-1)

营业执照

(副本)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　合肥卡迪生物药业有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　李光清

经营范围　第二类6840体外诊断试剂、第二类6864医用卫生材料及敷料、第一类医疗器械、消毒产品生产及销售；体外诊断试剂技术研发、咨询；电子元器件制造、销售；第二类医疗器械销售；化妆品、乳制品、保健食品、压片糖果、橡胶制品、卫生用品、预包装食品批发及零售；自营和代理各类商品、技术进出口业务（国家禁止和限制进出口的商品和技术除外）（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　贰佰叁拾万圆整

成立日期　2014年12月03日

营业期限　/长期

住　　所　肥东县经济开发区西外环西纬三路北侧3#厂房003幢

登记机关　肥东县市场监督管理局

2019 年 09 月 21 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：皖食药监械生产许20170003号

企业名称：合肥卡迪生物药业有限公司

生产地址：肥东县经济开发区西外环西纬三路北侧3#厂房003幢2楼

法定代表人：李光清

生产范围：Ⅱ类:6840 体外诊断试剂

企业负责人：陈正高

住　　所：肥东县经济开发区西外环西纬三路北侧3#厂房003幢

发证部门：安徽省药品监督管理局

有效期限：至 2022 年01 月15 日　　发证日期：2019 年 10 月 21 日

国家药品监督管理局制

第二类医疗器械经营备案凭证

备案编号：皖合食药监械经营备20170799号

企业名称	合肥卡迪生物药业有限公司
法定代表人	李光清
企业负责人	陈正高
经营方式	批零兼营
住　所	肥东县经济开发区西外环西纬三路北侧3#厂房003幢
经营场所	肥东县经济开发区西外环西纬三路北侧3#厂房003幢
库房地址	肥东县经济开发区西外环西纬三路北侧3#厂房003幢
经营范围	2002年分类目录：6801，6820，6821，6822，6823，6825，6826，6827，6840（诊断试剂不需低温冷藏运输贮存），6841，6854，6856，6857，6858，6864，6866

合肥市市场监督管理局 备案专用章

备案部门（公章）：安徽省合肥市

备案日期：2019年11月5日

QG07

中华人民共和国海关
报关单位注册登记证书

海关注册编码：3401965067

组织机构代码：322749970

企业名称：合肥卡迪生物药业有限公司

企业住所：肥东县经济开发区西外环西纬三路北侧3#厂房003幢

企业经营类别：进出口货物收发货人

注册登记日期：2018年8月2日

法定代表人：周凯

有效期：长期

注册海关：合肥海关

核发日期：2018年8月2日

中华人民共和国海关总署监制

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。