130 80 130

215

1-PRESENTATION OF PRODUCT

PRESENTATION OF BOX: 50PCS/BOX

GEMTIER™

Medical Face Mask

with Ear Loops

Soft & easy to breathe through

Fluid protection

Bacterial Filtration Efficiency (BFE) ⩾98%

Not made with natural rubber latex

50pcs Size: 17×9.5cm

EN 14683 Type IIR CE NON STERILE

GEMTIER™

The table below indicates the performance requirements defined by EN 14683-2019. This product meets European Standard EN 14683, Type IIR.

Test	Type I *	Type II	Type IIR
Bacterial filtration efficiency(BFE),(%)	⩾95	⩾98	⩾98
Differential pressure (Pa/cm²)	<40	<40	<60
Splash resistance pressure (kPa)	Not required	Not required	⩾16,0
Microbial cleanliness (cfu/g)	⩽30	⩽30	⩽30

Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

GEMTIER™

Medical Face Mask

with Ear Loops

Soft & easy to breathe through

Fluid protection

Bacterial Filtration Efficiency (BFE) ⩾98%

Not made with natural rubber latex

50pcs Size: 17×9.5cm

EN 14683 Type IIR CE NON STERILE

GEMTIER™

Gemtier Medical (Shanghai) Inc.
No.18 Jianding road,Fengjing town,Jinshan district, Shanghai 201502,China | www.gemtier.com
Email: sales@gemtier.com Made in China

EC REP
CMC MEDICAL DEVICES & DRUGS, S.L.
C/Horacio Lengo N°18
CP 29006, Málaga-Spain
info@cmcmedicaldevices.com

REF see the opening
LOT see the opening
see the opening
see the opening

PRESENTATION OF CARTON : 40BOX/CARTON

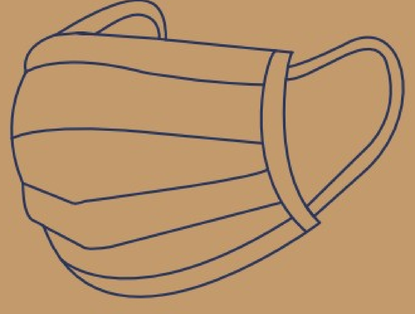
555mm

420mm

GEMTIER™

Medical Face Mask

with Ear Loops



2000pcs

GEMTIER™

Gemtier Medical (Shanghai) Inc.
No.18 Jianding road,Fengjing town,Jinshan district,
Shanghai 201502,China | www.gemtier.com
Email: sales@gemtier.com Made in China

EC REP

CMC MEDICAL DEVICES & DRUGS, S.L.
C/Horacio Lengo N°18
CP 29006, Málaga-Spain
info@cmcmedicaldevices.com

NON STERILE · Latex

2000pcs

Dimension: 55.5cm×44.5cm×42cm

445mm

PICTURE OF PALLET

2- CERTIFICATE

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145835 0001

Report No.: 15092033 007

Manufacturer:
Gemtier Medical (Shanghai) Inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
P.R. China

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60138645 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-01-19

Date: 2020-01-19

Notified Body

TÜVRheinland

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145835 0001
Report No.: 15092033 007

Manufacturer:
Gemtier Medical (Shanghai) Inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
P.R. China

Products:

- Sterile Syringes for Single Use
- Sterile Needles for Single Use
- Sterile Syringes with Needles for Single Use
- Vein Nutrition-providing Infusion Bags for Single Use
- Safety Infusion Sets for Single Use
- Safety I.V Needles for Single Use
- Infusion Sets for Single Use
- Extension Tube with Flow Regulator for Single Use
- Sterile Infusion Pump for Single Use
- Safety Blood Collection Device for Single Use
- Sterile Connection Tube for Single Use
- Disposable Safety Retractable Blood Collection Needles
- Bag-type Infusion Sets with Needle for Single use
- Disposable Safety Blood Collection Device With Retractable Needles

Site included:

No. 6469 Tingfeng Road, Fengjing Town,
Jinshan District, Shanghai 201502, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-01-19

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Gemtier Medical (Shanghai) inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-08-02
Certificate Registration No.:	SX 60138648 0001
An audit was performed. Report No.:	15092033 005
This Certificate is valid until:	2022-04-10

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-08-02

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de tuv com http //www.tuv com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60138648 0001
Report No.: 15092033 005

Organization:
Gemtier Medical (Shanghai) Inc.
No. 18 Jianding Road
Fengjing Town, Jinshan District
201502 Shanghai
China

Scope:

Products:
Sterile Syringes for Single Use, Sterile Needles for Single Use, Sterile Syringes with Needle for Single Use, Vein Nutrition-providing Infusion Bags for Single Use, Safety Infusion Sets for Single Use, Safety I.V. Needles for Single Use, Infusion Sets for Single Use, Extension Tubes with Flow Regulator for Single Use, Sterile Infusion Pumps for Single Use, Safety Blood Collection Device for Single Use, Sterile Connection Tubes for Single Use, Disposable Safety Retractable Blood Collection Needles, Bag-type Infusion Sets with Needle for Single use, Disposable Safety Blood Collection Device With Retractable Needles

Site included:
No. 6469 Tingfeng Road, Fengjing Town, Jinshan District, Shanghai 201502, China
Manufacture of Sterile Syringes for Single Use, Sterile Needles for Single Use, Sterile Syringes with Needle for Single Use

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-08-02

Fuxiu Sheng

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832662**

Certificate Holder:

Gemtier Medical (Shanghai) Inc.
Unified Social Credit Code: 91310116134206848C
Registration Address: No.18, Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Design and Development, Manufacturing and Distribution of Medical Devices, (Sterile Syringes for Single Use, Sterile Needles for Single Use, Vein Nutrition-providing Infusion Bags for Single Use, Sterile I.V. Needles for Single Use, Infusion Sets for Single Use, Extension Tubes with Flow Regulators for Single Use, Blood Transfusion Sets for Single Use, Sterile Infusion Pumps for Single Use, Safety Blood Collection Device for Single Use, Sterile Connection Tubes for Single Use, Sterile I.V. Catheters for Single Use)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2018-08-03 until 2021-08-02.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2018-08-07

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832662**

No.	Location	Scope
/01	Gemtier Medical (Shanghai) Inc. Unified Social Credit Code: 91310116134206848C Registration Address: No.18, Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, P. R. China Operation Address: same as above	Design Development and Manufacturing Distribution of Medical Devices (Sterile Syringes for Single Use, Sterile Needles for Single Use, Vein Nutrition-providing Infusion Bags for Single Use, Sterile I.V. Needles for Single Use, Infusion Sets for Single Use, Extension Tubes with Flow Regulators for Single Use, Blood Transfusion Sets for Single Use, Sterile Infusion Pumps for Single Use, Safety Blood Collection Device for Single Use, Sterile Connection Tubes for Single Use, Sterile I.V. Catheters for Single Use)
/02	Gemtier Medical (Shanghai) Inc. Unified Social Credit Code: 91310116134206848C Registration Address: No.18, Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, P. R. China Operation Address: No. 6469, Tingfeng Road, XingTa Town, Jinshan District, Shanghai 201502, P. R. China	Manufacturing of Medical Devices (Sterile Syringes for Single Use, Sterile Needles for Single Use)

2018-08-07

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832662/01**

Certificate Holder:

Gemtier Medical (Shanghai) Inc.
Unified Social Credit Code: 91310116134206848C
Registration Address: No.18, Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, P. R. China
Operation Address: same as above

Scope:

Design Development and Manufacturing Distribution of Medical Devices (Sterile Syringes for Single Use, Sterile Needles for Single Use, Vein Nutrition-providing Infusion Bags for Single Use, Sterile I.V. Needles for Single Use, Infusion Sets for Single Use, Extension Tubes with Flow Regulators for Single Use, Blood Transfusion Sets for Single Use, Sterile Infusion Pumps for Single Use, Safety Blood Collection Device for Single Use, Sterile Connection Tubes for Single Use, Sterile I.V. Catheters for Single Use)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate from 2018-08-03 until 2021-08-02.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2018-08-07

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832662/02**

Certificate Holder:

金塔®
Gemtier Medical (Shanghai) Inc.
Unified Social Credit Code: 91310116134206848C
Registration Address: No.18, Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, P. R. China
Operation Address: No. 6469, Tingfeng Road, XingTa Town, Jinshan District, Shanghai 201502, P. R. China

Scope: Manufacturing of Medical Devices (Sterile Syringes for Single Use, Sterile Needles for Single Use)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate from 2018-08-03 until 2021-08-02.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2018-08-07

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**Gemtier Medical（Shanghai）Inc.** No. 18, Jianding Road, Fengjing Town, Jinshan District 201502 Shanghai, China
Name and address of the European Authorized Representative	**CMC Medical Devices & Drugs, S.L.** C/Horacio Lengo N° 18, CP 29006, Málaga-Spain

We declare under our sole responsibility that

the medical device:	**Medical Face Masks**
Product code	NS2R-01，NS2R-02
Intended purpose	This product meets European Standard EN 14683, Type IIR. As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.
of class:	I

according to Annex VIII of Regulation (EU) 2017/745

meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration of conformity is valid in connection with the batch-related “final inspection report” of the device.

Conformity assessment procedure:	**EU Declaration of Conformity referred to in MDR Article 19**
Certificate:	**NA**
Notified Body:	**NA**

Shanghai, 2020-03-16

Place, date

Name and function

GEMTIER MEDICAL (SHANGHAI) 上海金塔医用器材有限公司 Sales Manager 中国上海 CHINA SHANGHAI

Instructions for Use
Medical Face Mask

CE GEMTIER™

Before using product, please read all information carefully

⚠ This mask helps to protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection.

Misuse may result in sickness or death.

Notice In case of any serious incident please report it to the manufacturer and your competent authority.

Before use, the wearer must read and understand these User Instructions. Keep these instructions for reference.

1.PRODUCT NAME

Medical Face Mask

2.DESCRIPTION/INDICATIONS

Medical face mask is a medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. Transmission of fluid-borne agents from patients to staff may occur via splashes.

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are e.g. noses and mouths of the surgical team. The main intended use of medical face masks is to protect the patients from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

These product meets the requirements of European Standard EN 14683:2019, Medical face masks– requirements and test methods. It is used to limit the transmission of infective agents exhaled by the wearer to the environment and patients. It also provides additional protection against the penetration of bodily fluids through the product.

Products are classified by bacterial filter efficiency and fluid resistance.

Performance tests include bacterial filtration efficiency (BFE), differential pressure, microbial cleanliness and splash resistance pressure.

The mask consists of a facepiece, two ear loops and a nose clip. The facepiece is composed of a filter layer that is moulded between two layers of non-woven fabric. The masks feature pleats or folds. Three pleats are used to allow the user to expand the mask such that it covers the area from the nose to the chin.

The medical face masks are developed according to ergonomic criteria offers the right solution for every face type and for every application.

The 3-layer construction provides effective protection against infections for patients and operating room personnel in accordance with Type IIR of EN 14683.

The inner site of the facepiece is white while the outer site is light blue.

The device is delivered in a nonsterile state. The shelf life is defined for 2 years after Production. A re-use by users is not allowed.

Medical face masks have the following characteristics:

-Flat-fold design provides convenient storage prior to use
-Lightweight, ear loop mask is easy to put on and remove
-It is comfortable and fits a wide range of wearers
-Effective filtration and easy breathing
-Splash resistant
-Latex free

Intended Purpose

This product meets European Standard EN 14683, Type IIR.

As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials.

Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

3.SPECIFICATION

Medical face masks specified in the European Standard EN 14683 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. The “R” signifies splash resistance.

This medical face mask is Type IIR mask acc. to EN 14683.

Table 1 — Performance requirements for medical face masks

Test	Type I	Type II	Type IIR
Bacterial filtration efficiency(BFE),(%)	⩾95	⩾98	⩾98
Differential pressure (Pa/cm^2)	＜40	＜40	＜60
Splash resistance pressure (kPa)	Not required	Not required	⩾16,0
Microbial cleanliness (cfu/g)	⩽30	⩽30	⩽30

4.CONTRAINDICATIONS

Do not use the medical face mask for respiratory protection for the wearer.

This mask is not intended for industrial use.

5.CAUTIONS and WARNINGS

· Inspect mask before the use to ensure that it is in good operating condition. Examine all the mask parts for signs of damage including the two ear loops, nose clip and facepiece material.

· Ensure there are no holes in the breathing zone and no damage has occurred.

· Avoid touching the inside of the mask with your hands.

· If you are concerned about the smell of the mask or feel it hard to breathe or feel nauseous, pls stop using immediately.

· If itching, spot rash or other symptoms occur, please stop using immediately.

· Discard after every use when the mask is used for surgical procedures. Follow national, state, local and facility infection control guidance and policies

· Change the mask timely. In general, surgical mask should not be reused. Replace the mask immediately if it is damaged or soiled, breathing

becomes difficult or contaminated with blood or body fluids.
· The mask should be disposed of immediately upon observation of damage or missing parts.
· Dispose of used product in accordance with applicable regulations.
· This is single-use device. A reprocessing and re-use of the device is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used.

6.DIRECTIONS FOR USE

- Open the package and take out the mask;
- Flatten the mask, with the blue side facing outwards, and push with both hands to the face with the nose clip uppermost;
- Wrap the mask band towards the base of the ear. Press the bendable nose clip gently to make the mask close to the face;
- Pull up and down the edge of the mask with both hands so that it covers under the eyes and chin.

7.STORAGE

Keep away from sunlight.
Avoid excessive heat (40°C or 104°F).
Relative Humidity: 0% to 80%

8.SHELF LIFE

2 years.

9.PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the device in accordance with accepted medical practice and applicable local, state and federal laws and regulations. Contaminated products should be disposed as hazardous waste in accordance with national regulations.

General information for users acc. to EN 14683 AnnexA

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. The majority of the nuclei are between 0,5µm and 12µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment. 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. The standard describes two types of medical face masks with associated protection levels. 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. Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements. 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. 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. Performance requirements for respirators are the scope of EN149. The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer' s face. Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result. The filtration capacity of mask materials can vary depending on the filter media. 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. 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. The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations. It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made. It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers. 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. The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures. 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. When there is a further need for protection then a new mask should be put on. 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. 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. Masks with very different performance are, however, available. Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.

10.EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE:

	Do not re-use		Keep dry
	Keep away from sunlight		Consult instructions for use
	Do not use if package is damaged		Non-sterile
	Caution	LOT	Batch Code
	Not made with natural rubber latex		Manufacturer
	Use-by date	REF	Catalog Number
EC REP	Authorized representative in the European Community		Date of manufacture

GEMTIER™

Manufactured by:
Gemtier Medical (Shanghai) Inc.

Address: No.18 Jianding Road, Fengjing Town, Jinshan District, Shanghai 201502, China
Website: www.gemtier.com Email: sales@gemtier.com Made in China

EC REP
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