

CE EN14683 DECLARATION OF CONFORMITY
欧盟符合性声明



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Version: A/0

Pages: 1/2

Technical File

Chapter: 3 EC Declaration of Conformity

Declaration of Conformity



Declaration of Conformity



According to the Medical Devices Directive 93/42/EEC

Manufacture:

ADD:



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Authorised representative:

Shanghai International Holding Corp. GmbH(Europe)

0.28Eiffelstrasse 80, 20537 Hamburg, German

Medical Device

Product Name
Disposable Face Mask

MOD-Classification : Class I, Rule 1

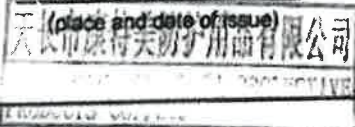
Lot/batches/Serial
number, Type, Periods
of manufacture : Various
(Where applicable)

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC (MDD).

This declaration of conformity is based on the European Medical Device Directive 93/42/EEC, Annex VII

General Manager

TIANCHANG 2020-3-17



(name and signature or equivalent marking of authorized person)

CE TECHNICAL DOCUMENTS REVIEW REPORT

CE 技术文件阅览报告



CE Technical Documentation Review Report

Manufacturer: 

Report Number: 15071895 001

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s): Disposable Underpads, Disposable Face Masks, Disposable Breast Pads, Disposable Caps, Disposable Bibs, Disposable Gowns, Disposable Shoe Covers

Type(s)/Model(s): Various Size

Classification: Class I, rule 1
(according to manufacturer's declaration)

Review result: During the examination of the provided Technical Documentation No. :
Disposable Underpads: TCKTM-001, Revision A/0, Date 2014-05-27
Disposable Face Masks: TCKTM-002, Revision A/0, Date 2014-05-30
Disposable Breast Pads: TCKTM-003, Revision A/0, Date 2014-05-27
Disposable Caps: TCKTM-004, Revision A/0, Date 2014-05-30
Disposable Bibs: TCKTM-005, Revision A/0, Date 2014-04-10
Disposable Gowns: TCKTM-006, Revision A/0, Date 2014-05-30
Disposable Shoe Covers: TCKTM-007, Revision A/0, Date 2014-05-30,
no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

Shanghai, 2014-06-18

TÜV Rheinland (Shanghai) Co., Ltd.


Xiaoli REN
Manager (Greater China Region)
Medical Services



Rev. 05, 2013-12-17

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● **PRODUCT PERFORMANCE**

NON-STERILE PRODUCTS, BFE ≥ 95%

● **SCOPE**

THE DISPOSABLE FACE MASK IS USED IN THE COMMON MEDICAL ENVIRONMENT WITHOUT BODY FLUID AND SPLASH RISK, OBSTRUCT THE CONTAMINANT FROM THE MOUTH.

● **USAGE**

1. TAKE OUT THE FACE MASK, ENSURE THE BRIDGE UP, HANG THE ELASTIC ON THE EAR, COVER THE FACE MASK FROM NOSE TO YOUR LOWER JAW.
2. FOLD THE BRIDGE TO "V" SHAPE IN ORDER TO FIT YOUR NOSE FULLY.
3. PLEASE PACK THE USED FACE MASK INTO THE PLASTIC BAG OR TISSUE, THROW IT INTO THE TRASH CAN WITH COVER.



● **HOW TO DISTINGUISH THE FRONT AND BACK SIDE?**

DARKER COLOR OUTSIDE, LIGHTER COLOR INSIDE.

● **CONTRAINDICATION**


NONE

● **NOTES**

1. FOR SINGLE USE ONLY.
2. DO NOT USE IF PACKING IS DAMAGED.
3. DO NOT USE WITH KNOWN HYPERSENSITIVITY.

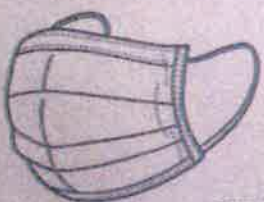
VALIDITY PERIOD: 3 YEARS.
MANUFACTURE DATE ON THE BOTTOM OF BOX
LOT NUMBER ON THE BOTTOM OF BOX

[Redacted]™

 **HIGH GRADE PROTECTIVE**
DESIGNED FOR LABORATORY/PROFESSIONAL MEDICAL CARE

DISPOSABLE FACE MASK

BFE **>95%** **TISSUE PROTECTION**



- THREE LAYER DESIGN WITH BROWN FABRIC
- GREATER FOLDY CUT LAYER BREATHABLE INNER LAYER
- SO TENSILE DESIGN FITS FOR YOUR FACE



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MASKS

 **M.Recht**
ACCESSORIES