# 广东省纺织团体标准技术委员会

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## 广东省纺织团体标准T/GDTEX 13-2020《一次性使用防疫口罩》英文参考版的说明

为满足会员企业和有关单位采用广东省纺织团体标准T/GDTEX 13-2020《一次性使用防疫口罩》（以下简称该标准）的需要，广东省纺织团体标准技术委员会对标准文本进行了翻译，完成了英文参考版，有关情况说明如下：

1、该标准的中文版本是全国团体标准平台公布的正式版本，该标准以中文版本为准，英文参考版本仅供参考，使用英文参考版本时如有疑义则以中文版本为准。

2、使用该标准的英文参考版时，应同时提标标准的中文版本，以便使用者随时查阅中文版本，确保标准使用的准确性和完整性。

3、广东省纺织团体标准采用简写GDTEX Organization standard，广东省纺织协会Guangdong Textile Association简称“GDTA”，广东省纺织团体标准技术委员会Guangdong Textile Organization standard Technical Commission简称“GDTEX”。

广东省纺织团体标准技术委员会

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# 广 东 省 纺 织 团 体 标 准

T/GDTEX 13—2020

# 一次性使用防疫口罩

**Disposable anti-epidemic mask**



2020-06-15 发布　　2020-06-20 实施

广东省纺织协会
广东省医疗器械行业协会　发布

# 前　言

本标准按照GB/T 1.1-2020给出的规则起草。

本标准由广东省医疗器械行业协会提出。

本标准由广东省医疗器械行业协会和广东省纺织团体标准技术委员会归口。

本标准起草单位：广东省医疗器械行业协会、广东省测试分析研究所（中国广州分析测试中心）、广东省纺织协会、广东思篙莱医疗器械科技有限公司、广州粤诚医疗器械有限公司、广州市科玮生物医药产业园有限公司、广州方舟创优科技有限公司、潮州市华祖食品有限公司、广东创刻康医疗科技有限公司 、广东康德商贸有限公司、深圳安创信科技有限公司、广州市易纬电子有限公司、广东同德药业有限公司、中山中测纺织产业技术研究中心、中山市纺织工程学会。

本标准主要起草人：范泽武、闵雯、黄明华、刘英丹、麦裔强、吴铨洪、彭必相、连希杰、林依妮。

请注意本标准的某些内容可能涉及专利。本标准的发布机构不承担识别这些专利的责任。

本标准文本可登录全国团体标准信息平台、广东省医疗器械行业协会和广东省纺织协会网站下载。

# 一次性使用防疫口罩

## 1 范围

本标准规定了一次性使用防疫口罩的术语和定义、产品分类、要求、试验方法、检验规则、产品质量控制、标志、包装、运输和储存。

本标准适用于一次性使用的防疫口罩。

本标准不适用于缺氧环境、水下作业、逃生、消防、医用及工业防尘等特殊行业用呼吸防护用品，不适用于 36 个月及以下婴幼儿使用，不适用于有呼吸阀的口罩。

## 2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅所注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 2912.1 纺织品 甲醛的测定 第 1 部分：游离和水解的甲醛（水萃取法）

GB/T 7573 纺织品 水萃取 pH 值的测定

GB/T 8170 数值修约规则与极限数值的表示和判定

GB/T 14233.1 医用输液、输血、注射器具检验方法第 1 部分：化学分析方法

GB/T 14233.2 医用输液、输血、注射器具检验方法第 2 部分：生物学试验方法

GB 15979 一次性使用卫生用品卫生标准

GB/T 16886.5 医疗器械生物学评价第 5 部分：体外细胞毒性试验

GB/T 16886.10 医疗器械生物学评价 第 10 部分：刺激与皮肤致敏试验

GB/T 16886.12 医疗器械生物学评价第 12 部分：样品制备与参照材料

GB/T 17592 纺织品 禁用偶氮染料的测定

GB 18401 国家纺织产品基本安全技术规范

YY 0469-2011 医用外科口罩

T/GDTEX 11 口罩弹性带

## 3 术语和定义

下列术语和定义适用于本文件。

3.1

**防疫口罩 anti-epidemic mask**

用于预防呼吸道传染疾病的口罩。

## 4 产品分类

4.1 口罩按照是否灭菌处理分为灭菌型和非灭菌型。

4.2 口罩按照形状分为平面型和立体型。

4.3 口罩按照规格分为小号、中号和大号。

## 5 要求

### 5.1 基本要求

5.1.1 口罩不应使用高毒性、致癌性或潜在致癌性物质以及已知的可导致皮肤刺激或其他不良反应的材料，其他限制使用物质的残留量应符合相关要求。

5.1.2 口罩应覆盖佩戴者的口鼻，应有良好的密闭性，并在佩戴过程中无明显的压迫感或压痛感，对头部活动影响较小。

5.1.3 口罩应配有鼻夹，鼻夹应采用塑性材料。

5.1.4 产品采用的弹性带应符合 T/GDTEX 11 的要求。

### 5.2 技术要求

技术要求分为内在质量和外观质量。内在质量包括：甲醛含量、pH 值、异味、可分解芳香胺染料、鼻夹长度、口罩带与口罩体连接点处断裂强力、环氧乙烷残留量、细菌过滤效率、压力差、微生物指标、生物学评价等。外观质量包括破损、污渍、完整性、规格等。

#### 5.2.1 内在质量要求

内在质量要求见表 1。

**表 1　内在质量要求**

| 项　目 | | | 要　求 |
|---|---|---|---|
| 甲醛含量/（mg/kg） | | | 按GB 18401 A类规定执行 |
| pH值 | | | |
| 异味 | | | |
| 可分解致癌芳香胺染料/（mg/kg） | | | |
| 鼻夹长度/cm | | ≥ | 5.0 |
| 口罩带与口罩体连接点处断裂强力/N | | ≥ | 10 |
| 环氧乙烷残留量[a]/（μg/g） | | ≤ | 10 |
| 细菌过滤效率（BFE）（%） | 初级 | ≥ | 95.00 |
| | 中级 | ≥ | 99.00 |
| | 高级 | ≥ | 99.97 |
| 压力差/(Pa/cm$^2$) | | ≤ | 49 |
| 微生物指标（非灭菌型） | 大肠菌群 | | 不得检出 |
| | 致病性化脓菌[b] | | 不得检出 |
| | 真菌菌落总数/（CFU/g） | ≤ | 100 |
| | 细菌菌落总数/（CFU/g） | ≤ | 200 |

表 1（续）

| 项　目 | | 要　求 |
|---|---|---|
| 微生物指标（灭菌型） | | 应无菌 |
| 生物学评价 | 细胞毒性/级　≤ | 2 |
| | 皮肤刺激性　≤ | 计分不超过0.4 |
| | 迟发型超敏反应/级　≤ | 1 |
| a 只考核经环氧乙烷灭菌处理的口罩。<br>b 指绿脓杆菌、金黄色葡萄球菌与溶血性链球菌。 | | |

5.2.2 外观质量要求

5.2.2.1 口罩外观应整洁、形状完好，表面不得有破损、污渍及其他明显缺陷。

5.2.2.2 口罩内层不得使用染色和印花面料，平面型口罩外层应有颜色、图案或其他区分标志。

5.2.2.3 口罩推荐规格如表 2。

表 2 口罩推荐规格

单位为毫米

| 口罩型号 | | 长度×宽度 |
|---|---|---|
| 平面型 | 小号 | 125×75 |
| | 中号 | 145×90 |
| | 大号 | 175×95 |
| 立体型 | 小号 | 120×60 |
| | 中号 | 135×70 |
| | 大号 | 150×90 |

## 6 试验方法

### 6.1 内在质量

6.1.1 pH 值试验按 GB/T 7573 规定执行。

6.1.2 甲醛含量按 GB/T 2912.1 规定执行。

6.1.3 异味按 GB 18401 规定执行。

6.1.4 可分解致癌芳香胺染料按 GB/T 17592 规定执行。

6.1.5 鼻夹长度

任取同规格的三个样品，取出鼻夹并平放于测量台上，用钢直尺或钢卷尺（分度值为 1mm）分别对鼻夹进行测量，以最低值作为最终结果。

6.1.6 口罩带与口罩体连接点处断裂强力

任取三个样品，按 YY 0469-2011 中 5.4.2 进行试验。

6.1.7 环氧乙烷残留量

经环氧乙烷处理的口罩按 GB/T 14233.1 中第 9 章规定执行。取平行样品测试，样品在口罩体上裁取。测试结果如一份合格，另一份不合格，不得平均计算，应重新取样测试，以最高值作为测试结果。结果计算以相对含量表示，保留一位小数。

6.1.8 细菌过滤效率（BFE）

任取三个样品，按 YY 0469-2011 中附录 B 进行试验。

6.1.9 压力差

任取五个样品，按 YY 0469-2011 中 5.7 进行试验。

6.1.10 微生物指标

根据样品标志，选择进行下述试验。非灭菌口罩按 GB 15979 中附录 B 规定执行，灭菌口罩按 GB/T 14233.2 第 3 章规定的无菌试验方法进行。

6.1.11 生物学评价

细胞毒性按 GB/T 16886.12 的条件制备浸提液，采用 GB/T 16886. 5 的方法进行。皮肤刺激按 GB/T 16886.12 的条件制备浸提液，采用 GB/T 16886.10 中规定的动物皮肤刺激试验进行。迟发型超敏反应按 GB/T 16886.12 规定的条件制备浸提液，采用 GB/T 16886.10 中规定的迟发型超敏反应最大剂量试验进行试验。

6.2 外观质量

6.2.1 任取 10 个样品进行试验，目视检查。检验光线以正常自然光为准，如以日光灯照明时，照度不低于 600lx。

6.2.2 规格尺寸测量，任取同规格 5 个样品，平放于测量台上，用钢直尺或钢卷尺(分度值为 1mm)进行测量。

## 7 检验规则

### 7.1 抽样

按交货批号的同一品种、同一规格（型号）的产品作为检验批次，从每检验批次产品中按试验要求随机抽取相应数量的样品，当同一批次产品数量大于 1 万个时，检验数量进行相应的加倍。

### 7.2 判定

产品不符合第5章（5.2.2.3除外）中所规定的任何一项质量要求时，该批产品判定为不合格。

## 8 产品质量控制

本标准要求对产品进行有效的质量控制，由本标准起草委员会认可的第三方检测机构提供全性能检验，日常生产质量检验可由认可的第三方实验室或认可的第三方授权第二方实验室进行产品质量抽检和飞检，每季度不少于一次，每年不少于五次。其中，第三方每年不少于一次。

## 9 标志

口罩最小包装应有清晰的中文标志，如果包装是透明的，应可以透过包装看到标志，标志内容至少包括：

a） 制造商名称、地址及联系方式；

b） 产品名称；

c） 主要原材料（内层、外层、过滤层）；

d） 执行标准；

e） 产品规格尺寸；

f） 使用说明（至少应包括正反面识别、佩戴方式等）；

g） 生产日期和（或）批号；

h） “一次性使用”字样或符号；

i） 如为灭菌产品应有相应的灭菌标志，并应注明所用的灭菌方法。

## 10 包装、运输和贮存

10.1 口罩应密封包装、口罩的包装应能防止破损和使用前的污染。

10.2 产品运输和装卸过程中，切勿拖曳、钩挂，避免损坏包装和产品。

10.3 产品应贮存在通风、干燥、清洁的库房内，并防蛀防霉。

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# GDTEX Organization standard

T/GDTEX 13—2020

# Disposable anti-epidemic mask

## 一次性使用防疫口罩

（English edition only provides a reference）



Release date: 2020-06-15 implementation date: 2020-06-20

GDTA and GD Medical Device Industry Association

# Introduction

This standard is drafted refer to the provision given in GB/T 1.1-2020.

This standard is proposed by Guangdong Medical Device Industry Association.

This standard is under the jurisdiction of Guangdong Medical Device Industry Association and Guangdong Textile Organization standard Technical Commission(GDTEX).

The Drafting unit of this standard: Guangdong Medical Device Industry Association, Guangdong Institute of Analysis(China National Analytical Center, Guangzhou), Guangdong Textile Association(GDTA), Guangdong sigaolai Medical Device Technology Co., Ltd., Guangzhou Yuecheng medical device Co., Ltd., Guangzhou Kewei biomedical Industrial Park Co., Ltd., Guangzhou Fangzhouchuangyou Technology Co., Ltd., Chaozhou Huazu Food Co., Ltd., and Guangdong chuangkekang Medical Technology Co., Ltd. , Guangdong Kant commerce and Trade Co., Ltd., Shenzhen anchuangxin Technology Co., Ltd., Guangzhou Yiwei Electronic Co., Ltd., Guangdong Tongde Pharmaceutical Co., Ltd. Zhongshan Textile Industry Technology Research Center of NACC. Zhongshan Textile Engineering Society

The Main drafters of this standard: fan Zewu, Min Wen, Huang Minghua, Liu Yingdan Mai yiqiang, Wu Quanhong, Peng Bixiang, Lian xijie, Lin Yini.

Please note that some contents of this standard may involve patents. The issuer of this standard is not responsible for identifying these patents.

The standard text can be downloaded from the websites of Guangdong Medical Device Industry Association and Guangdong Textile Association(GDTA).



**Any ambiguity arising from languages used in standard, the Chinese language shall prevail.**

# Disposable anti-epidemic mask

## 1 Scope

This standard specified the terms and definition,classification,requirements,test methods,test rule, quality control,labelling,packing,transportation and storage for disposable anti-epidemic mask.

This standard is applicable for disposable anti-epidemic mask.

This standard is not applicable for respiratory protection use of oxygen-deficient environment,underwater operation,escape,fire control,medical,industrial dust prevention and special industry. This standard is not applicable to baby at the age of and/under 36 months .and this standard is not applicable to masks which with respiratory value.

## 2 Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies, for undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 2912.1 Textiles-Determination of formaldehyde-Part 1: Free and hydrolyzed formaldehyde (water extraction method)

GB/T 7573 Textiles-Determination of pH of aqueous extract

GB/T 8170 Rules of rounding off for numerical values & expression and judgement of limiting values

GB/T 14233.1 Test methods for infusion, transfusion, injection equipments for medical use – Part 1: Chemical analysis methods

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use – Part 2: Biological test methods

GB 15979 Hygienic standard for disposable sanitary products

GB/T 16886.5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

GB/T 16886.10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

GB/T 16886.12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

GB/T 17592 Textiles - Determination of the banned azo colourants

GB 18401 National general safety technical code for textile products

YY 0469-2011 Surgical mask

T/GDTEX 11 Elastic band of Mask

## 3 Terms and definitions

For the purposes of this Standard, the following terms and definitions apply.

3.1 Anti-epidemic mask

Mask is for use to prevent respiratory tract infectious disease.

## 4 Classification

4.1 According to the sterilization function, classified into sterilized type and non-sterilized type.

4.2 According to the figuration of the mask, classified into planar and 3D shapes.

4.3 According to the specification of the mask,classified into small,middle and large size.

5 Requirements

5.1 Basic requirement

5.1.1 Masks should not be made of highly toxic, carcinogenic or potentially carcinogenic substances or materials known to cause skin irritation or other adverse reactions. Residues of other restricted substances should meet the relevant requirements.

5.1.2 The mask should cover the wearer's mouth and nose with good airtightness. There should be no obvious sense of pressure or tenderness in the process of wearing, and it has little effect on head movement

5.1.3 Mask should come with nose clip, and the nose clip should be made of plastic materials.

5.1.4 The elastic belt used in the mask shall meet the requirements of T/GDTEX 11.

5.2 Technical requirements

Technical requirements are classified into Intrinsic quality and appearance quality. Intrinsic quality includes formaldehyde content, pH value, odor, AZO dyes, nose clip length, breaking strength at the connection point between mask string and mask body, ethylene oxide residue, bacterial filtration efficiency, pressure differential, microbial index, biological evaluation, etc. Appearance quality includes damage, stain, integrity, specification, etc.

5.2.1 Intrinsic quality requirements

Table 1 performance quality requirements

| Item | | Requirements |
|---|---|---|
| Formaldehyde content /（mg/kg） | | Carry out according to GB 18401 A |
| pH Value | | |
| Odor | | |
| AZO dyes /（mg/kg） | | |
| Nose clip length /cm ≥ | | 5.0 |
| Breaking strength at the connection point between mask string and mask body /N ≥ | | 10 |
| Ethylene oxide residue [a]/（μg/g） ≤ | | 10 |
| Bacterial filtration efficiency （BFE)（%） | Primary ≥ | 95.00 |
| | Intermediate ≥ | 99.00 |
| | Senior ≥ | 99.97 |
| Pressure differential /(Pa/cm$^2$) ≤ | | 49 |
| Microbial content (non-sterilized type） | Coliform | Not detected |
| | Pathogenic Pyogenic bacteria [b] | Not detected |
| | Fungal colony counts / (CFU/g)≤ | 100 |
| | Bacterial colony counts (CFU/g)≤ | 200 |
| Microbial index（terilized type） | | Not detected |

Table 1(continued)

| | | |
|---|---|---|
| Biological evaluation | Cytotoxixity /grade ≤ | 2 |
| | Skin irritation ≤ | The score should not exceed 0.4 |
| | Delayed hypersensitivity /grade ≤ | 1 |
| a Only test mask which have treated ethylene oxide.<br>b Refer to Pseudomonas aeruginosa, staphylococcus aureus and hemolytic streptococcus | | |

5.2.2 Appearance quality requirements

5.2.2.1The appearance of the mask should be clean, intact, the surface should not be damaged, stained and have other obvious defects.

5.2.2.2 The inner layer of the mask shall not be made of dyed or printed fabric. The outer layer of the planar mask shall have color, pattern or other distinguishing marks.

5.2.2.3 the recommended sizes of mask in table 2.

Table 2 the recommended size of mask

Unit:mm

| Type of Mask | Size | Length × Width |
|---|---|---|
| Planar | Small | 125×75 |
| | Middle | 145×90 |
| | Large | 175×95 |
| 3-D shape | Small | 120×60 |
| | Middle | 135×70 |
| | Large | 150×90 |

6 Test methods

6.1 Intrinsic quality

6.1.1 pH Value test shall be carried out according to GB/T 7573.

6.1.2 Formaldehyde content shall be carried out according to GB/T 2912.1.

6.1.3 Odor test shall be carried out according to GB 18401.

6.1.4 AZO dyes test shall be carried out according to GB/T 17592.

6.1.5 The length of the nose clip

Take any three samples of the same specification, take out the nose clip and lay it flat on the measuring table. Measure the nose clip with a steel ruler or a steel tape (dividing value is 1mm), and take the lowest value as the final result.

6.1.6 Breaking strength at the connection point between mask string and mask body

Take 3 masks randomly as test specimen, and carry out the test according to YY 0469-2011 5.4.2.

6.1.7 Ethylene oxide residue

The masks treated with ethylene oxide shall be tested according to GB/T 14233.1. Take 2 masks and cut out from the mask body as test specimen. If one of the test results is qualified and the other one is unqualified, it shall not be calculated using the average, It shall be retest with another test specimen, and take the highest value as the test result. The result is expressed in terms of relative content, with one decimal place reserved.

6.1.8 Bacterial filtration efficiency (BFE)

Take 3 masks randomly and carry out the test according to YY 0469-2011 Appendix B.

6.1.9 Pressure differential

Take 5 masks and carry out test according to YY 0469-2011 5.7.

6.1.10 Microbial index

Choose test method according to the labeling on the mask, the test of non-sterilized mask shall be carried out according to GB 15979 appendix B, and the test of sterilized mask shall be carried out according to GB/T 14233.2 chapter 3 sterility test method .

6.1.11 Biological evaluation

For the cytotoxicity, the extraction solution shall be prepared under the condition according to GB/T 16886.12, shall be carry out the test according to GB/T 16886.5.

For the skin irritation, the extraction solution shall be prepared under the condition according to GB/T 16886.12, shall be carried out the test of the animal skin stimulation according to GB/T 16886.10.

For the delayed type hypersensitivity, the extraction solution shall be prepared under the conditions according to GB/T 16886.12, and shall be carried out the test of maximum dose according to GB/T 16886.10.

6.2 Appearance quality

6.2.1 take 10 masks randomly as test specimen， use visual inspection. Examine light shall be normal natural light, if use illuminated with fluorescent lamp, illuminance shall not be lower than 600lx.

6.2.2 Dimensional measurement, take 5 masks ramdomly,place it flat on the measuring table, use steel ruler or steel tape(dividing value is 1mm) for measurement.

7 Inspection rule

7.1 Sampling inspection

Products of the same variety and specification (model) of the delivery batch number shall be taken as the inspection batch, and the corresponding number of samples shall be randomly selected from each inspection batch according to the test requirements. When the number of products in the same batch is more than 10000, the inspection quantity shall be doubled accordingly.

7.2 Judgement

If products fail to meet any of the quality requirement in chapter 5(except 5.2.2.3), The batch of products is determined as unqualified.

8 Production quality control

This standard requires an effective quality control on products, all performance quality testing specified on this standard will be provided by the third party testing laboratory which is approved by drafting committee.Sample inspection and random quality inspection of daily production can be conducted by the third-party laboratory or the second party laboratory which approved by a third party authorized laboratory, such inspection to be conducted no less than once aseason, no less than five times a year.And such inspection by the third party shall not be less than once a year.

9 Labeling

There shall be necessary information on the individual package of the mask, and it shall be clear. If the package is transparent, the necessary information shall be visible through the package. The necessary information shall at least include the followings:

Manufacturer’s name, address and contact information;

a) Product name
b) Main raw materials (inner layer, outer layer, filter layer);
c) The implementation of standards;
d) the sizes of product;
e) Instructions for use (at least including front and back identification, wearing method, etc.)
f) Production date and/or lot number;
g) Words or symbols of "disposable use";
h) If it is a sterilized product, there should be corresponding sterilization mark and the sterilization method used should be indicated.

10 Packing, transportation and storage

10.1 The mask should be sealed and packed to prevent damage and contamination before use.
10.2 In the process of product transportation and loading and unloading, do not drag or hook to avoid damaging the package and product.
10.3 Products shall be store in a ventilated, dry and clean warehouse, and protected from moth and mildew.