

- The World Health Organization confirmed a covid-19 pandemic
- China has not banned the export of masks and/or other Anti-Epidemic products, nor has there been any news or written notice from China Customs regarding the forbidden export of masks
- China Gov/Customs supervise the Anti-Epidemic products export by 2 different Categories

Surgical/Medical Non-surgical/Medical

We will introduce the detailed requirement in below



Tips:

What are the applicable surgical /medical quality standard?

Surgical or medical	NON surgical or medical
YY/T0969-2013	EN-149
YY 0469-2011	EN-143
Gb 19083-2010	GB T32610
EN-14683	GB 2626-2006



3 Steps to confirm the qualification of Surgical / Medical mask (* and other Anti-Epidemic products) export

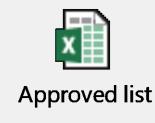
Step 1 :Approved list

Please check if your supplier's name in the approved list

You can find the most updated Approved list on the website http://www.nmpa.gov.cn/WS04/CL2582/

■ Step 2: Medical Device Production License
Please check If the manufacturer can provide
Medical Device Production License





Updated 6th of Apr





□ Step 3 :Medical Device Registration Certificate
Please check If the trading company
(* or the manufacturer have rights to export cargo)



can provide Medical Device Registration Certificate

If they can pass all the 3 steps check, your supplier is qualified to export the surgical /Medical mask (* and other Anti-Epidemic products)

P.S. They also need provide fully docs & declaration forms required for export

注册	正编号: 最級注准 20202140017
注册人名称	南温市地群医疗器械有限公司
过景人住所	南昌市进货县李渡世纪大道 216 号
生产地址	南昌市进资县李波世纪大进 26 年
代理人名称	1
代理人住所	1 CENED
产品名称	一次性使用口罩
型号、规格	A型: 挂耳式, B型: 胡带式, 规格: 大号、中号、小号。
结构及组成	本产品以需型粘合注章织造布为主要原材料经缝制成机压热台 制成、经环氧乙烷灭菌。产品无菌、
适用范围	供医疗机构使用:
附件	产品技术要求。
其他内容	1
& 15	表注册证号: · · · · · · · · · · · · · · · · · · ·



PAY MORE ATTENTION to NON-surgical/Medical mask

(* and other Anti-Epidemic products) export

China Gov/Customs is applying stricter supervision on NON-surgical/Medical mask by the measures of 100% manual document examination and inspection.

It is to avoid some suppliers selling/exporting to overseas Non-surgical/Medical category products that are finally be used as Surgical/Medical usage in overseas.

We have collected the following guidelines from customs but as the rules continue to evolve. It is important to ask client to request shippers to send us docs and Photos of Product marking, labeling, packaging to our Operations team in advance.



!!! PAY MORE ATTENTION to NON-surgical/Medical mask

- Product Test Report (CMA CNAS) and the Certificate of conformity
- ✓ The supplier must provide the Test Report (CMA CNAS)
- ✓ The supplier must provide the **Certification of Conformity** with company chop for testing, commodity name, quality standard, production date, Production batch, main components and period of validity

Correct



Wrong



- ✓ Each inner package must contain one Certificate of Conformity
- ✓ The test Report (CMA CNAS) must match the Certificate of conformity
- ✓ The quality standard must be listed on the test Report (CMA CNAS)

 Please note: No surgical or medical quality standard could used/listed.



检测编号: WJ20163901 Test No.

「州工业徽生物粒测甲心 EZHOU TESTING CENTER OF INDUSTRIAL MICROBIOLO もいる。日本

REPORT FOR ANAL

收样日期: 2016年11 Date Received	月 16 日	检测日期: 2016年11月25日 Date Analyzed			
样品名称 Name of Sample	强效除霉剂	样品来源 Source of Sample	送样		
委托单位 Applicant	深圳市绿泰环保科技有限公司	委托人 Client	彭吉元		
生产单位 Manufacturer	深圳市绿泰环保科技有限公司	样品等级 Sample grade	A		
型号规格 Type and Specification	500mL	商标 Brand	绿泰		
生产日期和批号 Date and Batch Number of Production	201610/20161025	样品数量 Quantity of Sample	1 67		
样品状态 State of Sample	液体	样品包装 Packing of Sample	瓶装		
检验依据和方法 Standard and Methods	《消毒技术规范》(2002 年版)2.1.1.9 真菌定量条灭试验				
检测项目 Items of Analysis	杀菌效果 (黑曲霉 ATCC 16404)				
各注 Remarks	作用浓度: 原液, 作用时间: 9h				

样品编号	作用时间	试验苗种	阳性对照样 菌落数(cfu/mL)	试验样菌落数 (cfu/mL)	杀灭率 (%)	杀灭 对数值
WJ20163901-1	9h	黑曲霉	4.15×10 ⁶	<1	>99.99	≥4.00
			3.50×10 ⁶	<1	>99.99	≥4,00
			3.95×10 ⁶	<1	>99.99	≥4.00

可判定为消毒合格。 以下空白 Blank Below

检测结果:

制: 犯程子 申核: 对记节 蓋效 Litor来华子 Checker Issuer

※ 変数日期(2 Date Reporte



PAY MORE ATTENTION to NON-surgical /Medical mask

☐ Labeling and marks

- "NO surgical/medical mask" "非医用口罩" should be printed on the sales package
- "FDA" can not be printed on the products/package for the Non-surgical /Medial mask If "CE"/"KN" is printed on the products/package for the Non-surgical/Medial mask. It must be followed by the non-surgical quality standard

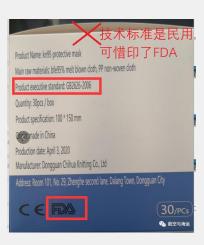
MEDICAL USE PROHIBITE







Wrong







PAY MORE ATTENTION to NON-surgical /Medical mask

- Inner package
- ✓ The NON-surgical/medical Mask's inner package must be contained in Good Quality sales package

Correct





Wrong



