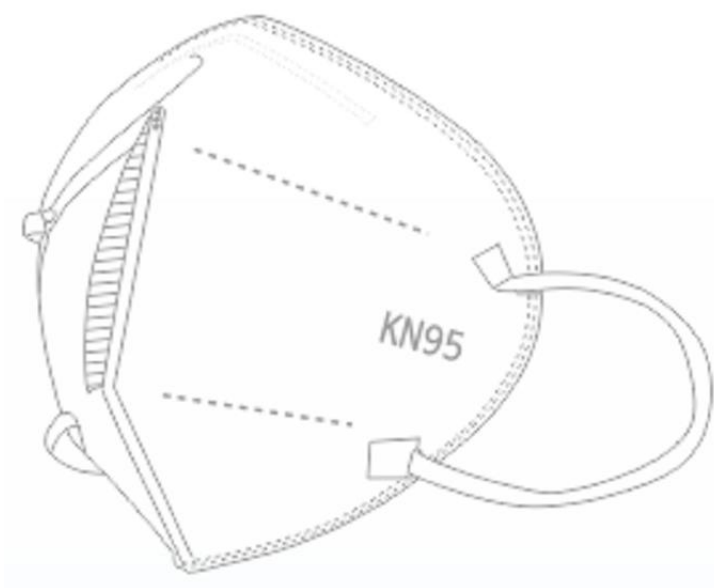




先达医疗



-KN95防护口罩-

东莞市先达医疗器械有限公司

Dongguan Xianda Medical Devices Co., Ltd.

公司资料更新止9/27



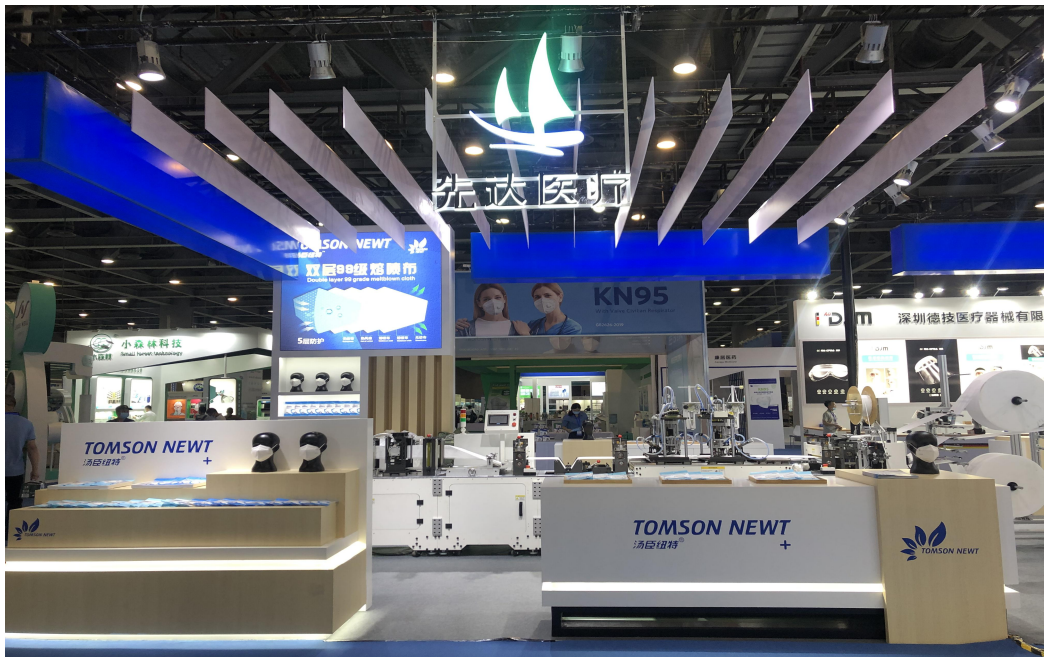
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东莞市先达医疗器械有限公司占地面积5000平方米，公司具有专业的生产、销售和管理团队。目前公司拥有全自动KN95防护口罩生产线设备200余条，日产KN95防护口罩量可达200余万个。先达KN95防护口罩具备完善的认证资质，包含美国FDA、德国EUA、德凯、国标GB2626-2006等认证。疫情期间先达KN95防护口罩远销意大利、美国、德国、土耳其等30余个国家和地区。

Dongguan Xianda Medical Equipment Co., Ltd. covers an area of 5,000 square meters. The company has a professional production, sales and management team. At present, the company has more than 200 automatic KN95 protective mask production lines and the daily production of KN95 protective masks can reach more than 10 million. Xianda KN95 protective masks have completed certifications, including American FDA, German EUA, DEKRA, GB2626-2006 and other certifications. During the epidemic, Xianda KN95 protective masks were exported to more than 30 countries and regions including Italy, the United States, Germany, and Turkey.





# 广州国际防疫物资展会

Guangzhou International Anti-epidemic Materials Exhibition



# 广州国际防疫物资展会

Guangzhou International Anti-epidemic Materials Exhibition





\* 4 4 0 4 2 9 1 8 2 \*



## 营业执照

(副本) (副本号:1-1)

统一社会信用代码  
91441900MA54B7M091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 东莞市先达医疗器械有限公司  
类型 有限责任公司(自然人独资)  
法定代表人 陈仁凤  
经营范围 销售:医疗器械;生产、销售:日用口罩(非医  
用)、劳保用品;货物或技术进出口(国家禁止  
或涉及行政审批的货物和技术进出口除外)。(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 人民币叁佰万元  
成立日期 2020年02月11日  
营业期限 长期  
住所 广东省东莞市石碣镇石碣龙眼路40  
号7号楼301室



登记机关



2020年3月9日

### 海关进出口货物收发货人备案回执

企业名称	东莞市先达医疗器械有限公司
统一社会信用代码	91441900MA54B7M091
海关备案日期	2020-03-18
海关编码	4419960ZAV
检验检疫备案号	5654200489
有效期	长期



自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台” (<http://credit.customs.gov.cn>) 或者“互联网+海关” (<http://online.customs.gov.cn>) 查询海关公示的企业信息。



# 4.2

# 公司资质

Company qualification



## 对外贸易经营者备案登记表

备案登记表编号: 04828203

统一社会信用代码: 91441900MA54B7M091

进出口企业代码: -----

经营者中文名称	东莞市先达医疗器械有限公司		
经营者英文名称	Dongguan Xianda Medical Equipment Co., Ltd		
组织机构代码	-----	经营者类型 (由备案登记机关填写)	有限责任公司
住所	广东省东莞市石碣镇石碣龙眼路40号7号楼301室		
经营场所 (中文)	广东省东莞市石碣镇石碣龙眼路40号7号楼301室		
经营场所 (英文)	Room 301, Building 7, No. 40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province		
联系电话	18688855790	联系传真	-----
邮政编码	523299	电子邮箱	745839489@qq.com
工商登记注册日期	2020-2-11	工商登记注册号	-----

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	陈仁凤	有效证件号	440882199406182416
注册资金	叁佰万元	(折美元)	

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

企业法定代表人/ 个体工商户负责人姓名		有效证件号	
企业资产/个人财产		(折美元)	

备注	
----	--

填表前请认真阅读背面的条款,并由企业法定代表人或个体工商户负责人签字、盖章。



2020

年08月17日

# 4.3

# 公司资质

Company qualification



第 38109058 号



## 商标注册证

**汤臣纽特**

核定使用商品/服务项目（国际分类：10）

第10类：医疗器械和仪器；阴道冲洗器；耳鼻喉科器械；已杀菌消毒的医疗器械；牙科设备和仪器；医疗用超声器械；医用冷敷贴；吸奶器；避孕套；缝合材料（截止）

注册人 杨乔220622198304240029

注册人地址 辽宁省沈阳市苏家屯区胜利大街香醇波尔多小区

注册日期 2020年01月21日 有效期至 2030年01月20日

局长



申长雨

发证机关





5

# 德国EUA-中国商务部白名单

## German EUA-China Ministry of Commerce White List

30  
1982-2012



中国医药保健品进出口商会  
服务产业链 | 助力国际化

English 登陆 | 注册

请输入关键词进行搜索



开具不可抗力相关事实性证明

取得国外认证和注册企业查询

首页

关于商会

新闻中心

行业服务

权威发布

商会会刊

企业风采

会员之家

加入商会

### 取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

东莞市先达医疗器械有限公司

检索

企业名称 (中文)	企业名称 (英文)	产品类别	统一社会信用代码	国外注册认证情况
东莞市先达医疗器械有限公司	Dongguan Xianda Medical Equipment Co., Ltd.	非医用口罩	91441900MA5487M091	德国EUA

#### 友情链接

政府部门

行业组织

国际机构

行业门户

关于我们 | 联系我们 | 会员之家 | 行业服务

地址: 北京市东城区朝阳门内大街南竹杆胡同6号 (北京INN大厦3号楼) 11-12层

版权所有: 中国医药保健品进出口商会 未经许可, 不得转载

互联网药品信息服务资格证编号: (京) -非经营性-2020-0090 京ICP备:06034461号-1 京公网安备 11010102002916号



医保商会官方微信

中国商务部旗下  
中国医药保健品进出口商会官网查询:  
<http://www.cccmhpie.org.cn/>



# 美国疾控中心 CDC 检测数据



CDC test data of the US Centers for Disease Control

CDC Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives. Protecting People™

All A-Z Topics

Search NIOSH

The National Personal Protective Technology Laboratory (NPPTL)

NIOSH > NPPTL > Respirator Assessments to Support COVID-19 Response

NPPTL

What's New on the NPPTL Website

A to Z Index

For Respirator Users

For Respirator Manufacturers

Respirator Assessments to Support COVID-19 Response

Beyond Shelf Life/Stockpiled Respirator Assessment Request

Beyond Shelf Life/Stockpiled Assessment Results

Promoting productive workplaces through safety and health research

## NPPTL Respirator Assessments to Support the COVID-19 Response

Updated May 8, 2020

### International Assessment Results – Not NIOSH-approved

NPPTL has completed International Assessments for the products listed below.

NPPTL makes no representation as to the authenticity of the samples received and assessed. As part of its standard respirator approval process for NIOSH-approved respirators, NPPTL conducts a comprehensive quality assurance review of the quality process and manufacturing site. None of these reviews were conducted during this limited assessment. Further, no certificates of approval were provided with the samples. Therefore, validation of the claims that the product meets a particular international standard cannot be made.

<a href="#">Workplace Safety &amp; Health Topics</a>	Dongguan Xianda Medical Equipment Co., Ltd.	KN95 Protective Mask	GB2626	99.63	99.47	<a href="#">2020-120.1</a>
<a href="#">Publications and Products</a>	Flyhorse Industrial Co., Ltd.	FL 0616	EN149	92.58	90.18	<a href="#">2020-75.1</a>
<a href="#">Programs</a>	Gaomi City Hancheng Personal Protective Products Co., Ltd.	Baokangjie 9001	GB2626	99.15	98.19	<a href="#">2020-57.3</a>

# 俄罗斯紧急授权书

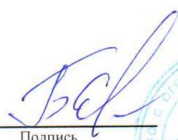
## Russian emergency authorization

Орган по сертификации продукции Общества с ограниченной ответственностью "Центр испытаний и метрологии"

наименование органа по сертификации, включая организационно-правовую форму  
Место нахождения: 117545, РОССИЯ, город Москва, улица Дорожная, дом 8 корпус 1, К1-103  
Фактический адрес: 117545, РОССИЯ, город Москва, улица Дорожная, дом 8 корпус 1, К1-103  
Телефон/Факс: +7 9773643357/ Адрес электронной почты: metr.center@gmail.com  
ОГРН 1167746434338

адрес, телефон, факс, ОГРН(ИП)  
Аттестат аккредитации № RA.RU.11NB32 срок действия с 01.08.2019  
выдан Федеральной службой по аккредитации

регистрационный номер аттестата аккредитации, когда и кем выдан



Подпись



**УТВЕРЖДАЮ**  
Руководитель органа по сертификации  
продукции  
**Е.И. Белякина**  
инициалы, фамилия

### РЕШЕНИЕ ПО ЗАЯВЛЕНИЮ № 02208 от 18.05.2020 г.

В результате рассмотрения заявления №02208 от 18.05.2020г.

Общество с ограниченной ответственностью "ТАМОЖЕННЫЙ ЦЕНТР КАЧЕСТВА"

наименование заявителя - юридического лица, ФИО индивидуального предпринимателя  
Межрайонная инспекция Федеральной налоговой службы № 46 по г. Москве 04.09.2013, ОГРН  
1137746798771

сведения о регистрации организации или индивидуального предпринимателя  
Место нахождения (адрес юридического лица): 125080, Россия, город Москва, шоссе  
Волоколамское, Дом 1, Строение 1, Эт 5 П Vi К 306 Оф 76  
Телефон: +74951201830, Адрес электронной почты: log@c-qc.com

место нахождения (юридический адрес) и фактический адрес (включая наименование страны), телефон, факс, адрес электронной почты

**о регистрации декларации о соответствии продукции требованиям технического(-их)  
регламента(-ов) Таможенного союза (ЕАЭС):**

Маски KN95. Модель DGXD-325. Продукция изготовлена в соответствии с технической  
документацией изготовителя.

полное наименование продукции, включая сведения, обеспечивающие ее идентификацию, а также наименование и реквизиты документа, в соответствии с которыми изготовлена продукция

наименование ТР ТС (ЕАЭС), на соответствие требованиям которого проводится подтверждение соответствия в форме декларирования

Код(ы) ТН ВЭД ЕАЭС (ТС) 6307909800

Серийный выпуск

наименование объекта декларирования - серийный выпуск (с указанием срока действия) / партия (с указанием размера партии) / единичное изделие (с указанием заводского № изделия), а также реквизиты товаросопроводительной документации (при наличии), с указанием № и даты заключения контракта/договора, инвойса/спецификации и др.

**Изготовитель продукции:**

"DONGGUAN XIANDA MEDICAL EQUIPMENT CO., LTD"

полное наименование изготовителя

Место нахождения (адрес юридического лица): Китай, Room301, building 7, No. 40 Longyan Road,  
Shijie Town, Dongguan City, GUANDONG

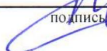
место нахождения (юридический адрес) и фактический адрес, - для юридического лица и его филиалов, которые производят продукцию, или место жительства - для физического лица, зарегистрированного в качестве индивидуального предпринимателя

### ОРГАНОМ ПО СЕРТИФИКАЦИИ ПРОДУКЦИИ ПРИНЯТО РЕШЕНИЕ:

**1. Отказать в регистрации декларации о соответствии заявленной продукции требованиям:**

наименование ТР ТС (ЕАЭС), нормативных документов с указанием разделов (пунктов, подпунктов), предусмотренных данным (-ми) ТР ТС (ЕАЭС), иных документов  
на основании: ТР ТС 017 2011 Техническому регламенту Таможенного союза «О безопасности продукции легкой промышленности», ТР ТС 019/2011 Технический регламент Таможенного союза "О безопасности средств индивидуальной защиты" не распространяются на заявленную продукцию.

Эксперт



подпись

В.Л. Никаншин

инициалы, фамилия



**Fiscal Year 2020**

## **CERTIFICATION OF REGISTRATION**

This certifies that:

**DONGGUAN XIANDA MEDICAL EQUIPMENT CO., LTD**

**Room 301, building 7, No. 40 Longyan Road, Shijie Town, Dongguan City,  
GUANGDONG, 523300, CHINA**

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

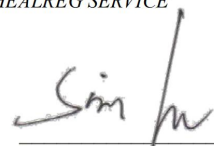
**HEALREG SERVICE INC**

**Owner/Operator Number: 10063282**

**Device Listing#: See annex**

*HEALREG SERVICE INC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HEALREG SERVICE INC 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. HEALREG SERVICE INC assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.*



Chief engineer

Issued: March 19, 2020

Expiration Date: December 31, 2020

# 德凯DEKRA认证符合性声明

## Declaration of conformity with DEKRA certification



**Bewertung der Konformität von Corona SARS-Cov-2 Pandemie Atemschutz (CPA) nach dem Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Revision 1**

**Evaluation of the conformity of corona sars-cov-2 pandemic respiratory protection (CPA) according to the testing principle for corona sars-cov-2 pandemic respiratory protection masks revision 1**

Berichtsnummer <i>Report number</i>	3417213.10-CPA
Prüfgegenstand <i>Test subject</i>	Corona SARS-CoV-2 Atemschutzmaske <i>Corona SARS-CoV-2 respiratory protective mask</i>
Modell <i>Type</i>	TOMSON NEWT KN95 Protective Mask
Hersteller <i>Manufacturer</i>	Dongguan Xianda Medical Equipment Co., Ltd. Room 301, building 7, No.40 Longyan Road Shijie Town, Dongguan City Guangdong Province 523300 P.R. China
Importeur <i>Importer</i>	Dongguan Xianda Medical Equipment Co., Ltd. Room 301, building 7, No.40 Longyan Road Shijie Town, Dongguan City Guangdong Province 523300 P.R. China

Die Anforderungen des Prüfgrundsatzes sind

*The requirements of the test principle are*

✓
Erfüllt <i>Fulfilled</i>

Die technische Wirksamkeit des oben genannten Produkts ist im Rahmen der Empfehlung (EU) 2020/403 der Europäischen Kommission vom 13. März 2020 über Konformitätsbewertungs- und Marktüberwachungsverfahren im Kontext der COVID-19 Bedrohung zu vermuten.  
*The technical efficiency of the above-mentioned product is to be presumed within the framework of the European Commission Recommendation (EU) 2020/403 of 13<sup>th</sup> March 2020 on conformity assessments and market surveillance procedures in the context of the COVID-19 risk.*

Der Prüfgrundsatz kann unter dem folgenden Link eingesehen werden:

*The test principle can be accessed under the following link:*

<http://www.zls-muenchen.de/aktuell/index.html>

Diese Bewertung ist gültig vom 28.04.2020 bis 27.04.2021.

*This evaluation of conformity is valid from 2020-04-28 until 2021-04-27.*

DEKRA Testing and Certification GmbH  
Bochum, 28.04.2020

  
Jörg-Timm Kilisch  
Geschäftsführer *Managing Director*



Seite / Page 2 - 2

Diese Bewertung darf nur vollständig und unverändert weiterverbreitet werden.  
This evaluation of conformity may only be published in its entirety and without any change.

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart  
Zertifizierungsstelle: Dinnendahlstraße 9, 44809 Bochum,  
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com





**DEKRA Testing and Certification GmbH**  
**Standort Essen**  
**Persönliche Schutzausrüstungen**

Adlerstraße 29  
45307 Essen, Germany

Tel +49.201.52319-0  
Fax +49.201.52319-401  
E-Mail DTC-Support-Essen@dekra.com

### Prüfbericht / Test report No. 3417213.10-CPA

<b>Prüfgegenstand</b> <i>Testsubject</i>	Corona SARS-CoV-2 Atemschutzmaske <i>Coroan SARS-CoV-2 respiratory protective mask</i>
<b>Modell</b> <i>Type</i>	TOMSON NEWT KN95 Protective Mask
<b>Hersteller</b> <i>Manufacturer</i>	Dongguan Xianda Medical Equipment Co., Ltd. Room 301, building 7, No.40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, 523300, China
<b>Prüfgrundlage</b> <i>Test requirement</i>	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 <i>Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26</i>
<b>Prüfergebnis</b> <i>Test result</i>	Die Pandemie Atemschutzmaske entspricht den Corona SARS-CoV-2 Prüfanforderung <i>The pandemic respiratory protective mask does meet the Corona SARS- CoV-2 test requirement.</i>
<b>Datum</b> <i>Date of issue</i>	28.04.2020

Dieser Bericht besteht aus 10 Seiten. *This report consists of 10 pages.*

Eine auszugsweise Veröffentlichung dieses Berichtes bedarf der Zustimmung der DEKRA Testing and Certification GmbH. Juristisch bindend ist ausschließlich die deutsche Fassung dieses Berichtes.

*Publication of extracts of this report requires agreement of DEKRA Testing and Certification GmbH. We confirm the correctness of the translation of the German original. In the case of arbitration however only the German wording shall be valid and binding.*

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart  
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# 德凯DEKRA认证符合性声明

Declaration of conformity with DEKRA certification



## Veranlassung / Reason

<b>Auftragseingang</b> <i>Date of order</i>	14/04/2020
<b>Auftraggeber</b> <i>Applicant</i>	Dongguan Xianda Medical Equipment Co., Ltd. Room 301, building 7, No.40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, 523300, China
<b>Importeur</b> <i>Importer</i>	Dongguan Xianda Medical Equipment Co., Ltd. Room 301, building 7, No.40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, 523300, China
<b>Eingang der Prüfmuster</b> <i>Date of receipt of test item</i>	23/04/2020
<b>Prüfzeitraum</b> <i>Date (s) of performance of tests</i>	24/04/2020 – 27/04/2020
<b>Prüfstandort</b> <i>Test location</i>	DEKRA Testing and Certification GmbH Persönliche Schutzausrüstungen Adlerstraße 29 45307 Essen, Germany

## Zusammenfassung der Prüfung / Summary of Testing


Prüfung	bestanden <i>pass</i>	nicht bestanden <i>fail</i>	nicht anwendbar <i>not applicable</i>
2.2 Sichtprüfung / <i>Visual inspection</i>	✓		
2.3 Anlegeprüfung / <i>Donning test</i>	✓		
2.4 Durchlass des Filtermediums / <i>Penetration of the filter medium</i>	✓		
2.5 Ausatemventil(e) / <i>Exhalation valve(s)</i>	✓		
2.6 Atemwiderstand / <i>Breathing resistance</i>			
2.6.1 CPA ohne Ventil / <i>CPA without valve</i>	✓		
2.6.2 CPA mit Ventil / <i>CPA with valve</i>			✓
2.7 Kennzeichnung und Informationen des Hersteller <i>Marking and manufacturer's information</i>	✓		

### Bemerkung / Remarks:

Die Konformitätsaussage ist „Erfüllt“, wenn der ermittelte Messwert kleiner oder gleich dem vorgegebenen Grenzwert ist.

*The conformity verdict is "Fulfilled" if the measured value is less or equal to the limit.*

DEKRA Testing and Certification GmbH

  
(Stockmann)  
Prüfingenieur/ *Test engineer*



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### 1 Bezug der Prüfergebnisse / Reference of the test results

Die in diesem Bericht aufgeführten Ergebnisse beziehen sich ausschließlich auf die untersuchten Prüfmuster.  
*The results listed in this report refer only to the tested samples.*

Für die Prüfung wurden folgende Dokumente zugrunde gelegt:  
*The following documents were taken as a basis for the tests:*

1	Verpackung / packaging
---	------------------------

Die folgende Maske wurde geprüft / *The following mask was tested:*



Verpackung / Packaging



Aufschrift / Label



Nasenbügel / Nose clip



Seitenansicht / Side view

# 德凯DEKRA认证符合性声明

Declaration of conformity with DEKRA certification



Frontansicht / Front view



Innenansicht / Inner view

## 2 Prüfergebnisse / Test results

### A Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken / Testing principle for Corona SARS-CoV-2 pandemic respiratory masks

Die nachfolgenden Ziffern entsprechen den Abschnitten des Prüfgrundsatzes für Corona SARS-Cov-2 Pandemie Atemschutzmasken.

The following numbers correspond to the paragraphs of the testing principle for Corona SARS-CoV-2 pandemic respiratory masks.

## 2 Anforderungen und Prüfungen / Requirements and tests

### 2.1 Übersicht der Prüfungen / Overview of tests

Prüfung Test	Anzahl Muster Number samples	Konditionieren Conditioning	Abschnitt Section EN 149
Temperaturkonditionierung Temperature conditioning	5	--	8.3.2 nur only a)
Gebrauchssimulation Simulation of wearing	5	--	8.3.1
Sichtprüfung Visual inspection	1	--	--
Anlegeprüfung Donning test	1	--	8.4.1
Atemwiderstand (Geräte ohne Ventil) Breathing resistance (valveless devices)	2	T.C. + S.W. (2)	8.9.2 + 8.9.3
Ausatemventil-Durchströmung Exhalation valve flow	2	--	8.3.4
Atemwiderstand (Geräte mit Ventil) Breathing resistance (valved devices)	2	T.C. + S.W. + F.C. (2)	8.9.2 + 8.9.3
Durchlass des Filtermediums Flow rate through the filter medium	3	T.C. + S.W. (3)	8.11



### 2.2 Sichtprüfung / Visual inspection

CPA müssen zum Verkauf so verpackt angeboten werden, dass sie gegen mechanische Beschädigung und Verunreinigung vor dem Gebrauch geschützt sind.

*When supplied for purchase, the CPA must be packed in such a way that they are protected against mechanical damage and contamination prior to their use.*

<b>Ergebnis:</b> <i>test result:</i>	Die Verpackung schützt die Maske vor mechanischer Beschädigung und Verunreinigungen. <i>The package protects the mask from mechanical damage and contamination.</i>	<b>Erfüllt</b> <i>Fulfilled</i>
		✓

### 2.3 Anlegeprüfung / Donning test

Die CPA muss leicht an- und abgelegt werden können. Die Kopfbänderung muss kräftig genug sein, um die CPA in Position zu halten. Die CPA muss einen Dichtsitz am Gesicht der Testperson gewährleisten. Bei einem Trageversuch dürfen keine offensichtlichen Undichtigkeiten im Bereich der Dichtlinie der Maske erkennbar sein. Bei der Beatmung durch eine Testperson dürfen keine Luftströmungen, die durch Undichtigkeiten in der Dichtlinie (schlechte Anpassung an das Gesicht) entstehen, wahrnehmbar sein.

*Putting on and removing the CPA must be done easily. The head straps must be strong enough to keep the CPA in place. The CPA must ensure a close fit at the face of the test person. When carrying the mask in a test, no obvious leakage along the sealing line of the mask shall be recognisable. When the test person uses the mask for breathing, no air flow shall be noticeable which is caused by leakage in the sealing line (poor facial fit).*

<b>Ergebnis:</b> <i>test result:</i>	Die Kopfbänderung besteht aus dünnen flexiblen Bändern und die CPA konnte leicht angelegt und abgenommen werden. <i>The headgear consists of thin flexible straps and the CPA was easy to put on and take off.</i>	<b>Erfüllt</b> <i>Fulfilled</i>
		✓

<b>Ergebnis:</b> <i>test result:</i>	Die Kopfbänderung ist kräftig genug, um die CPA in Position zu halten. <i>The headgear is strong enough to hold the CPA in place.</i>	<b>Erfüllt</b> <i>Fulfilled</i>
		✓

<b>Ergebnis:</b> <i>test result:</i>	Bei einem Trageversuch waren bei 1 von 3 Versuchen offensichtliche Undichtigkeiten im Nasenbereich der CPA erkennbar. <i>During a wearing test, obvious leaks were detected in the area of the nose of the CPA in 1 of 3 tests.</i>	<b>Erfüllt</b> <i>Fulfilled</i>
		✓



### 2.4 Durchlass des Filtermediums / Penetration of the filter medium

Der Durchlass des Filters der CPA wird mit Paraffinöl mit 95 l/min geprüft. Es müssen insgesamt drei Muster der CPA geprüft werden. Die drei Muster werden wie folgt konditioniert: Temperaturkonditionierung nur bei hoher Temperatur und Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt nach EN 149:2001+A1:2009 Abschnitt 8.11 mit der Prüfung des Durchlasses nach EN 13274-7:2008 Abschnitt 5.1 und 5.2. Der Durchlass der CPA aller drei Muster muss  $\leq 6,0$  % sein.

*The penetration through the filter of the CPA is tested using paraffin oil at 95 l/min. In total, three samples of the CPA have to be tested. The three samples will be conditioned as follows: temperature conditioning only at high temperature, and simulation of wearing with moist respiration for 20 minutes. The test is carried out in accordance with section 8.11 of EN 149:2001+A1:2009 with the filter penetration according to EN 13274-7:2008 clause 5.1 and 5.2. The penetration of the CPA of all three samples must be  $\leq 6.0$  %.*

**Tabelle I Ergebnisse beim Kurztest (3 min) / Table I Results during short test (3 min)**

Probe Sample <sup>1</sup>	Konditionierung Conditioning	Durchlassgrad bei 95 l/min Paraffinöl Penetration at 95 l/min Paraffine oil [%]	
		Anforderung Requirement	Ergebnis Test result
01	T.C. + S.W.	$\leq 6,0$ %	2,73
02	T.C. + S.W.		2,47
03	T.C. + S.W.		2,29

<sup>1</sup> Vom Prüflabor verwendete Bezeichnung. *Designation used by the testing laboratory.*  
T.C.: Temperatur konditioniert / *Temperature conditioned*  
S.W.: Gebrauchssimulation / *Usage simulation*



### 2.5 Ausatemventil(e) / Exhalation valve(s)

Die CPA darf ein oder mehrere Ausatemventil(e) haben. Sie müssen in jeder Lage richtig funktionieren. Die Prüfung muss nach EN 149:2001+A1:2009 Abschnitt 8.9.1 erfolgen. Falls ein Ausatemventil(e) vorhanden ist, muss es (müssen sie) nach einem 30 s dauernden kontinuierlichen Ausatemstrom von 300 l/min weiter richtig funktionieren. Die Prüfung erfolgt während der Messung des Atemwiderstandes. Wenn das Gehäuse des Ausatemventils am Maskenkörper befestigt ist wird mit einer gefühlten Kraft von 10 N per Hand an dem Ausatemventil bzw. an dessen Gehäuse gezogen. Löst sich das Ventil, gilt die Prüfung als nicht bestanden.

*The CPA may have one or more exhalation valves; these must work properly in any position. The test has to be carried out in accordance with section 8.9.1 of EN 149:2001+A1:2009. If one or more exhalation valves are in place, they must continue to work properly after a continuous exhalation flow of 300 l/min for 30 s. The test is carried out during the measurement of the breathing resistance. Once the casing of the exhalation valve has been fastened to the mask body, the exhalation valve or its casing is manually pulled with a felt force of 10 N. If the valve comes loose, the test is deemed as not passed.*

<b>Ergebnis:</b> test result:	Die CPA beinhaltet kein(e) Ausatemventil(e). <i>The CPA does not include (an) exhalation valve(s).</i>	<b>Erfüllt</b> Fulfilled
		✓

### 2.6 Atemwiderstand / Breathing resistance

Die Atemwiderstände gelten für CPA mit und ohne Ventil(e).

*The breathing resistance requirements apply to valved and valveless CPA.*

#### 2.6.1 CPA ohne Ventil / CPA without valve

Geprüft werden zwei CPA nach der Temperaturkonditionierung und der Gebrauchssimulation mit feuchter Beatmung für 20 Minuten. Die Prüfung erfolgt in Anlehnung an EN 149:2001+A1:2009 Abschnitt 8.9. Der Ausatemwiderstand wird in der Lage geradeaus sehend geprüft.

Der Atemwiderstand bei der Einatmung bei 95 l/min muss bei allen Mustern  $\leq 3,0$  mbar sein.

Der Atemwiderstand bei der Ausatmung bei 160 l/min muss bei allen Mustern  $\leq 3,0$  mbar sein.

*2 CPA are tested after the temperature conditioning and the simulation of wearing with moist respiration for 20 minutes. The test is carried out following section 8.9 of EN 149:2001+A1:2009. The exhalation resistance is tested in the position "looking straight ahead".*

*The breathing resistance for inhalation at 95 l/min must be  $\leq 3.0$  mbar at all samples.*

*The breathing resistance for exhalation at 160 l/min must be  $\leq 3.0$  mbar at all samples.*



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**Tabelle II Ergebnisse der Einatemwiderstandsmessungen bei 95 l/min**  
*Table II Results of inhalation resistance measurements at 95 l/min*

Probe Sample <sup>1</sup>	Konditionierung Conditioning	Einatemwiderstand Inhalation resistance [mbar]	
		Anforderung Requirement	Ergebnis Test result
04	T.C. + S.W.	≤ 3,0 mbar	1,4
05	T.C. + S.W.		1,35

<sup>1</sup> Vom Prüflabor verwendete Bezeichnung / Designation used by the testing laboratory.  
T.C.: Temperaturkonditioniert / Temperature conditioned  
S.W.: Gebrauchssimulation / Usage simulation

**Tabelle III Ergebnisse der Ausatemwiderstandsmessungen bei 160 l/min**  
*Table III Results of exhalation resistance measurements at 160 l/min*

Probe Sample <sup>1</sup>	Konditionierung Conditioning	Ausatemwiderstand Exhalation resistance [mbar]	
		Anforderung Requirement	Ergebnis Test result
04	T.C. + S.W.	≤ 3,0 mbar	2,3
05	T.C. + S.W.		2,2

<sup>1</sup> Vom Prüflabor verwendete Bezeichnung. / Designation used by the testing laboratory.  
T.C.: Temperaturkonditioniert / Temperature conditioned  
S.W.: Gebrauchssimulation / Usage simulation

Gemessen in der ersten definierten Lage des Prüfkopfes / Measured in the first defined position of the test head:  
geradeaussehend / facing directly ahead

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# 德凯DEKRA认证符合性声明

## Declaration of conformity with DEKRA certification



### 2.7 Kennzeichnung und Informationen des Hersteller / Marking and manufacturer's information

Die Kennzeichnung der CPA oder der kleinsten Verpackungseinheit soll dokumentiert werden, sodass eindeutig erkennbar ist, welche CPA vorliegt.

*The marking of the CPA or the smallest packing unit must be documented so that it becomes unmistakably clear which CPA is provided.*

Ergebnisse / Test Results		
	Erfüllt Fulfilled	Nicht erfüllt not fulfilled
Die CPA oder die kleinste Verpackungseinheit muss mit den folgenden Informationen gekennzeichnet sein: <i>The marking of the CPA or the smallest packing unit must contain the following information:</i>		
a) Name, Warenzeichen oder andere Angaben zur Identifikation des Herstellers; <i>a) Name, trademark and/or other details identifying the manufacturer;</i>	✓	
b) Typidentische Kennzeichnung (Nummer, Modell oder Ähnliches) <i>b) Marking identifying the type (number, model or similar)</i>	✓	
Informationen müssen jeder CPA oder der kleinsten Verpackungseinheit beigelegt sein. Die Informationen können in Textform oder beispielsweise in Piktogrammen dargestellt werden. Die Informationen müssen mindestens Angaben enthalten zu: <i>Information must be supplied with each CPA or smallest packing unit. This information can be displayed either as text or as pictograms, for example. The information must also provide at least details on:</i>		
a) Sitz sowie richtiges An- und Ablegen; <i>a) Fit and correct putting on and removing of the mask;</i>	✓	
b) Hinweise zur Verwendung <i>b) Instruction on its use</i>	✓	

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## CE检验报告

## CE Test Report



LGAI Technological Center, S.A. (APPLUS)  
Campus UAB - Ronda de la Font del Carme s/n  
08193 Bellaterra (Barcelona)  
T +34 93 567 20 00  
www.applus.com



Notified Body No. 0370

## CERTIFICADO DE EXAMEN UE DE TIPO

### EU-TYPE EXAMINATION CERTIFICATE



No. **0370-4185-PPE/B**

<b>ORGANISMO NOTIFICADO Nº</b> <i>NOTIFIED BODY NUMBER</i>	<b>0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)</b>
<b>SOLICITANTE</b> <i>APPLICANT</i>	<b>DONGGUAN XIANDA MEDICAL EQUIPMENT CO., LTD</b> Room301, building 7, No. 40 Longyan Road, Shijie Town, Dongguan City, GUANGDONG
<b>FABRICANTE</b> <i>MANUFACTURER</i>	<b>DONGGUAN XIANDA MEDICAL EQUIPMENT CO., LTD</b> Room301, building 7, No. 40 Longyan Road, Shijie Town, Dongguan City, GUANGDONG
<b>REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD   APPLICABLE REGULATION TO GIVE CONFORMITY:</b> <b>REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL</b> <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
<b>PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD</b> <i>CONFORMITY ASSESSMENT PROCEDURE</i>	Módulo // <i>Module</i> : <b>B</b> <b>EXAMEN UE DE TIPO   EU TYPE EXAMINATION</b>
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: DGXD-325 PROTECTIVE MASK (non-medical)
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b> <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	Esta media máscara está fabricada sólo para la protección del COVID 19 <i>This filtering half mask is manufactured for COVID-19 protection only</i>
<b>NORMAS APLICABLES   APPLICABLE STANDARDS</b>	PPE-R/02.075 version 2 Filtering half mask to protect against COVID-19
<b>FECHA DE EMISIÓN   ISSUE DATE</b>	<b>11/08/2020</b>
<b>VALIDEZ HASTA   VALIDITY UNTIL</b>	<b>11/08/2021</b>
El presente certificado se mantendrá vigente durante 1 año siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425, de acuerdo con la recomendación de la Comisión Europea (EU) 2020/403 para su uso por parte del personal sanitario. <i>This certificate will remain valid for 1 year as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425, according to the recommendation 2020/403 for its use by healthcare professionals.</i>	

**Applus<sup>+</sup>**  
 LGAI Technological Center, S.A.  
 Xavier Ruíz Peña  
 Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.  
*This document is not valid without its technical annex, whose number coincides with the number of certificate.*

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Technical Annex Ed. 1  
11/08/2020

### ANEXO TÉCNICO TECHNICAL ANNEX

0370-4185-PPE/B

### I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

<b>MARCA</b> <i>BRAND</i>	TOMSON NEWT
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: DGXD-325 PROTECTIVE MASK (non-medical)
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b> <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	Esta media máscara está fabricada sólo para la protección del COVID 19 <i>This filtering half mask is manufactured for COVID-19 protection only</i>
<b>INFORME DE ENSAYO</b> <i>TEST REPORT</i>	S20071502301E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. (NTEK)

No. FZ2005879


 中国认可  
国际互认  
检测  
TESTING  
CNAS L0153


# 检测报告

## TEST REPORT

委托方	东莞市先达医疗器械有限公司
生产单位	东莞市先达医疗器械有限公司
样品名称	KN95 防护口罩
型号规格	---
检测类别	委托检测


**广东产品质量监督检验研究院**

GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

No. FZ2005879

广东产品质量监督检验研究院  
GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

## 检测报告

## TEST REPORT



报告随机号: HGX8447

第 1 页 共 5 页

样品名称	KN95 防护口罩		样品编号	YFZ20/005879
	送样 (√)	抽样 (/)		
商标	汤臣纽特 TOMSON NEWT		型号规格	---
委托方	东莞市先达医疗器械有限公司		检测类别	委托检测
委托方地址	广东省东莞市石碣镇石碣龙眼路 40 号 7 号楼 301 室		产品编号/批号	---
生产单位	东莞市先达医疗器械有限公司		抽样单编号	---
受检单位	---		生产日期	---
抽样单位	---		样品数量	50(个)
抽样地点	---		抽样基数	---
抽样日期	---		检验地点	本部实验室
收样日期	2020 年 03 月 19 日		检验日期	2020 年 03 月 19 日~ 2020 年 03 月 24 日
检测依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》			
判定依据	---			
检测结论	<p>本次委托检测共检 4 项, 所检项目符合标准的要求。</p> <p style="text-align: right;">             (检验检测专用章)            签发日期: 2020 年 03 月 24 日            (Q1)         </p>			
备注	报告中的“---”表示此项不适用, 报告中“/”表示此项空白。			

批准:



审核:



主检:



No. FZ2005879

## 检 测 报 告

### TEST REPORT

第 2 页 共 5 页

序号	检测项目[单位]	标准条款	标准要求	检测结果	单项结论	备注	
1	过滤效率[%]	5.3	KN95 $\geq$ 95.0	未预处理	99.90	合格	/
					99.80		
					99.92		
					99.80		
					99.90		
					99.90		
					99.80		
					99.80		
					99.91		
					99.92		
				预处理	99.80		
					99.92		
					99.90		
			99.80				
氯化钠颗粒物检测 温度：(25 $\pm$ 5)℃ 湿度：(30 $\pm$ 10)%			实测温度：24℃ 实测湿度：34%				
2	吸气阻力[Pa]	5.5	总吸气阻力 $\leq$ 350	未预处理	131.7	合格	/
					138.6		
				预处理	127.9		
					129.6		
3	呼气阻力[Pa]	5.5	总呼气阻力 $\leq$ 250	未预处理	108.7	合格	/
					109.6		
				预处理	104.7		
					103.7		

No. FZ2005879

## 检测报告

TEST REPORT

第 3 页 共 5 页

序号	检测项目[单位]	标准条款	检测结果	单项结论	备注	
4	可燃性	5.13	暴露于火焰的各部件在从火焰移开后, 不应燃烧; 如果燃烧, 续燃时间不应超过 5s	未预处理	合格	/
				未出现燃烧现象		
				未出现燃烧现象		
				未出现燃烧现象		
预处理	未出现燃烧现象					
未出现燃烧现象						



No. FZ2005879

检测 报告

TEST REPORT

第 4 页 共 5 页



样品描述

/

型号规格或其它说明

/

No. FZ2005879

## 检测 报 告

TEST REPORT



第 5 页 共 5 页

附注：

- 1、试验地点：广州市黄埔区科学城科学大道 10 号
- 2、委托单位地址及邮编：广东省东莞市石碣镇石碣龙眼路 40 号 7 号楼 301 室
- 3、检测环境条件：检测项目均在相应标准规定的条件下进行（有注明的除外）
- 4、抽样程序（如适用）：-----
- 5、偏离标准方法的说明（如适用）：-----
- 6、检测结果不确定度说明（如适用）：-----
- 7、分包项目及分包方（如适用）：-----

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广东省深圳市南山区红花岭工业区闽利达工业园2楼

编号: QHJ2004029701/CH

第 1 页 共 13 页

发行日期: 2020 年 04 月 30 日

## 测试报告

申请商 : 东莞市先达医疗器械有限公司  
地址 : 广东省东莞市石碣镇石碣龙眼路 40 号 7 号楼 301 室

制造商 : 东莞市先达医疗器械有限公司  
地址 : 广东省东莞市石碣镇石碣龙眼路 40 号 7 号楼 301 室

样品名称 : KN95 防护口罩  
样品型号 : 折叠型  
样品商标 : 汤臣纽特

收样日期 : 2020 年 04 月 26 日  
测试日期 : 2020 年 04 月 26 日 ~ 2020 年 04 月 30 日

测试要求 : 根据客户要求, 按照欧洲化学品管理署 (ECHA) 于 2020 年 1 月 16 日及之前公布的 205 种高度关注物质 (SVHC) 清单(根据欧盟第 (EC) No 1907/2006 号 REACH 法规) 进行测试;  
于 2020 年 3 月 3 日进行咨询的候选清单中的五种高度关注物质;

测试方法 : 请参见后续页  
测试结果 : 请参见后续页  
结论 : 根据具体的测试项目和测试方法所得结果, 样品中的 205 种高度关注物质 (SVHC) 的含量都低于 0.1%。

完成:



梁素宁

审核:



周兵

中检(深圳)环境技术服务有限公司

批准:



杨任游





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编号: QHJ2004029701/CH

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发行日期: 2020 年 04 月 30 日

测试结果:

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
1	二氯化钴 #	7646-79-9	231-589-4	未检出	0.01
2	五氧化二砷 #	1303-28-2	215-116-9	未检出	0.005
3	三氧化二砷 #	1327-53-3	215-481-4	未检出	0.005
4	砷酸氢铅 #	7784-40-9	232-064-2	未检出	0.005
5	三乙基砷酸酯 #	15606-95-8	427-700-2	未检出	0.005
6	重铬酸钠二水合物 #	7789-12-0	234-190-3	未检出	0.005
7	三丁基氧化锡 (TBTO) #	56-35-9	200-268-0	未检出	0.005
8	葱	120-12-7	204-371-1	未检出	0.005
9	4,4-二氨基二苯基甲烷 (MDA)	101-77-9	202-974-4	未检出	0.005
10	六溴环十二烷(HBCDD)	25637-99-4 3194-55-6	247-148-4 221-695-9	未检出	0.01
	α - HBCDD	134237-50-6	—		
	β - HBCDD	134237-51-7	—		
	γ - HBCDD	134237-52-8	—		
11	二甲苯麝香	81-15-2	201-329-4	未检出	0.01
12	邻苯二甲酸 (2-乙基己基酯) (DEHP)	117-81-7	204-211-0	未检出	0.01
13	邻苯二甲酸二丁酯(DBP)	84-74-2	201-557-4	未检出	0.005
14	邻苯二甲酸丁苯酯(BBP)	85-68-7	201-622-7	未检出	0.005
15	短链氯化石蜡 (C10-13) (SCCPs)	85535-84-8	287-476-5	未检出	0.005
16	葱油	90640-80-5	292-602-7	未检出	0.01
17	葱油、葱糊、轻油	91995-17-4	295-278-5	未检出	0.01
18	葱油、葱糊、葱馏分	91995-15-2	295-275-9	未检出	0.01



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发行日期: 2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
19	葱油、少葱	90640-82-7	292-604-8	未检出	0.01
20	葱油、葱糊	90640-81-6	292-603-2	未检出	0.01
21	高温煤焦油、沥青	65996-93-2	266-028-2	未检出	/
22	2,4-二硝基甲苯	121-14-2	204-450-0	未检出	0.01
23	邻苯二甲酸二异丁酯(DIBP)	84-69-5	201-553-2	未检出	0.01
24	铬酸铅 #	7758-97-6	231-846-0	未检出	0.01
25	钼铬红 (CI 颜料红 104) #	12656-85-8	235-759-9	未检出	0.01
26	铅铬黄 (CI 颜料黄 34) #	1344-37-2	215-693-7	未检出	0.01
27	磷酸三(2-氯乙基)酯	115-96-8	204-118-5	未检出	0.01
28	丙烯酰胺	79-06-1	201-173-7	未检出	0.01
29	三氯乙烯	79-01-6	201-167-4	未检出	0.01
30	硼酸 #	10043-35-3 11113-50-1	233-139-2 234-343-4	未检出	0.01
31	无水四硼酸钠 #	1303-96-4 1330-43-4 12179-04-3	215-540-4	未检出	0.01
32	七水合四硼酸钠 #	12267-73-1	235-541-3	未检出	0.01
33	铬酸钠 #	7775-11-3	231-889-5	未检出	0.01
34	铬酸钾 #	7789-00-6	232-140-5	未检出	0.01
35	重铬酸铵 #	7789-09-5	232-143-1	未检出	0.01
36	重铬酸钾 #	7778-50-9	231-906-6	未检出	0.01
37	硫酸钴 #	10124-43-3	233-334-2	未检出	0.01
38	硝酸钴 #	10141-05-6	233-402-1	未检出	0.01
39	碳酸钴 #	513-79-1	208-169-4	未检出	0.01



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发行日期: 2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL (%)	
40	醋酸钴 #	71-48-7	200-755-8	未检出	0.01	
41	2-甲氧基乙醇	109-86-4	203-713-7	未检出	0.01	
42	2-乙氧基乙醇	110-80-5	203-804-1	未检出	0.01	
43	三氧化铬#	1333-82-0	215-607-8	未检出	0.01	
44	三氧化铬及其低聚物产生的酸 铬酸, 二铬酸, 铬酸及二铬酸的低聚物#	铬酸 #	7738-94-5	231-801-5	未检出	0.01
		重铬酸 #	13530-68-2	236-881-5	未检出	
		铬酸和重铬酸的低聚物 #	—	—	未检出	
45	乙二醇乙醚醋酸酯	111-15-9	203-839-2	未检出	0.01	
46	铬酸铈 #	7789-6-2	232-142-6	未检出	0.01	
47	1,2-苯二酸-二(C7-11支链与直连)烷基(醇)酯	68515-42-4	271-084-6	未检出	0.01	
48	联氨	7803-57-8 302-01-2	206-114-9	未检出	0.01	
49	1-甲基-2-吡咯烷酮	872-50-4	212-828-1	未检出	0.01	
50	1,2,3-三氯丙烷	96-18-4	202-486-1	未检出	0.01	
51	1,2-苯二酸-二(C6-8支链)烷基酯(富C7)	71888-89-6	276-158-1	未检出	0.01	
52	铬酸铬 #	24613-89-6	246-356-2	未检出	0.01	
53	氢氧化铬酸锌钾 #	11103-86-9	234-329-8	未检出	0.01	
54	锌黄 #	49663-84-5	256-418-0	未检出	0.01	
55	硅酸铝耐火陶瓷纤维 #	—	—	未检出	0.05	
56	氧化锆硅酸铝耐火陶瓷纤维 #	—	—	未检出	0.05	
57	甲醛苯胺共聚物	25214-70-4	500-036-1	未检出	0.01	
58	邻苯二甲酸二甲氧乙酯	117-82-8	204-212-6	未检出	0.005	
59	邻氨基苯甲醛	90-04-0	201-963-1	未检出	0.005	



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No.	测试项目	CAS No.	EC No.	结果 (%)	MDL (%)
60	对特辛基苯酚	140-66-9	205-426-2	未检出	0.005
61	1,2-二氯乙烷	107-06-2	203-458-1	未检出	0.005
62	二乙二醇二甲醚	111-96-6	203-924-4	未检出	0.005
63	砷酸 #	7778-39-4	231-901-9	未检出	0.01
64	砷酸钙 #	7778-44-1	231-904-5	未检出	0.01
65	砷酸铅 #	3687-31-8	222-979-5	未检出	0.01
66	N,N-二甲基乙酰胺 (DMAC)	127-19-5	204-826-4	未检出	0.005
67	酚酞	77-09-8	201-004-7	未检出	0.005
68	2,2'-二氯-4,4'-二氨基二苯基甲烷 (MOCA)	101-14-4	202-918-9	未检出	0.005
69	叠氮化铅 #	13424-46-9	236-542-1	未检出	0.01
70	2,4,6-三硝基苯二酚铅 #	15245-44-0	239-290-0	未检出	0.01
71	苦味酸铅 #	6477-64-1	229-335-2	未检出	0.01
72	三甘醇二甲醚	112-49-2	203-977-3	未检出	0.005
73	1, 2-二甲氧基乙烷	110-71-4	203-794-9	未检出	0.005
74	三氧化二硼 #	1303-86-2	215-125-8	未检出	0.01
75	甲酰胺	75-12-7	200-842-0	未检出	0.01
76	甲基磺酸铅(II) #	17570-76-2	401-750-5	未检出	0.005
77	异氰尿酸三缩水甘油酯	2451-62-9	219-514-3	未检出	0.005
78	替罗昔隆	59653-74-6	423-400-0	未检出	0.005
79	4,4'-四甲基二氮二苯酮	90-94-8	202-027-5	未检出	0.005
80	4,4'-亚甲基双(N,N-二甲基苯胺)	101-61-1	202-959-2	未检出	0.005
81	结晶紫	548-62-9	208-953-6	未检出	0.005



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发行日期: 2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
82	碱性蓝26	2580-56-5	219-943-6	未检出	0.005
83	溶剂蓝4	6786-83-0	229-851-8	未检出	0.005
84	$\alpha,\alpha$ -二[(二甲氨基)苯基]-4-氨基苯甲醇	561-41-1	209-218-2	未检出	0.005
85	3-乙基-2-甲基-2-(3-甲基丁基)噁唑烷	143860-04-2	421-150-7	未检出	0.01
86	2,4-二氨基甲苯	95-80-7	202-453-1	未检出	0.005
87	N-甲基乙酰胺	79-16-3	201-182-6	未检出	0.01
88	氧化铅与硫酸铅的复合物	12065-90-6	235-067-7	未检出	0.005
89	4-氨基联苯	92-67-1	202-177-1	未检出	0.005
90	二硝丁酚(地乐酚)	88-85-7	201-861-7	未检出	0.01
91	双(十八烷基)二氧化三铅 #	12578-12-0	235-702-8	未检出	0.005
92	硝酸铅 #	10099-74-8	233-245-9	未检出	0.005
93	三碱式硫酸铅 #	12202-17-4	235-380-9	未检出	0.005
94	氧化铅 #	1317-36-8	215-267-0	未检出	0.005
95	钛酸铅 #	12060-00-3	235-038-9	未检出	0.005
96	4,4'-二氨基-3,3'-二甲基二苯甲烷	838-88-0	212-658-8	未检出	0.005
97	碱式乙酸铅 #	51404-69-4	257-175-3	未检出	0.005
98	硫酸二甲酯	77-78-1	201-058-1	未检出	0.01
99	呋喃	110-00-9	203-727-3	未检出	0.005
100	颜料黄41 #	8012-00-8	232-382-1	未检出	0.005
101	四乙基铅 #	78-00-2	201-075-4	未检出	0.005
102	二盐基邻苯二甲酸铅 #	69011-06-9	273-688-5	未检出	0.005
103	硫酸二乙酯	64-67-5	200-589-6	未检出	0.01





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发行日期：2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
104	氨基氰铅盐 #	20837-86-9	244-073-9	未检出	0.005
105	掺杂铅的硅酸钡 #	68784-75-8	272-271-5	未检出	0.005
106	磷酸氧化铅 #	12141-20-7	235-252-2	未检出	0.005
107	邻甲基苯胺	95-53-4	202-429-0	未检出	0.005
108	邻氨基偶氮甲苯	97-56-3	202-591-2	未检出	0.005
109	对氨基偶氮苯	60-09-03	200-453-6	未检出	0.005
110	2-甲氧基-5-甲基苯胺	120-71-8	204-419-1	未检出	0.005
111	二丁基锡 #	683-18-1	211-670-0	未检出	0.001
112	钛酸铅锆 #	12626-81-2	235-727-4	未检出	0.005
113	环氧丙烷	75-56-9	200-879-2	未检出	0.01
114	溴代正丙烷	106-94-5	203-445-0	未检出	0.005
115	碱式碳酸铅 #	1319-46-6	215-290-6	未检出	0.005
116	C16-18-脂肪酸铅盐 #	91031-62-8	292-966-7	未检出	0.005
117	四氧化三铅 #	1314-41-6	215-235-6	未检出	0.005
118	亚硫酸铅 (II) #	62229-08-7	263-467-1	未检出	0.005
119	4,4'-二氨基二苯醚及其盐类	101-80-4	202-977-0	未检出	0.01
120	碱式硫酸铅 #	12036-76-9	234-853-7	未检出	0.005
121	氟硼酸铅 #	13814-96-6	237-486-0	未检出	0.005
122	硅酸铅 #	11120-22-2	234-363-3	未检出	0.005
123	十溴联苯醚	1163-19-5	214-604-9	未检出	0.001
124	分支或线性的壬基酚	—	—	未检出	0.01
125	偶氮二甲酰胺	123-77-3	204-650-8	未检出	0.01



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No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
126	辛基酚聚醚-9	—	—	未检出	0.01
127	乙二醇二乙醚	629-14-1	211-076-1	未检出	0.01
128	甲基六氢苯酚	25550-51-0	247-094-1	未检出	0.01
	4-甲基六氢苯酚	19438-60-9	243-072-0		
	甲基六氢化邻苯二甲酸酐	48122-14-1	256-356-4		
	3-甲基六氢苯二甲酯酐	57110-29-9	260-566-1		
129	六氢邻苯二甲酸酐	85-42-7	201-604-9	未检出	0.005
		13149-00-3	236-086-3		
		14166-21-	238-009-9		
130	支链和直链1, 2-苯二羧二戊酯	84777-06-0	284-032-2	未检出	0.005
131	邻苯二甲酸正戊基异戊基酯	—	776297-69-9	未检出	0.005
132	全氟代十四酸	376-06-7	206-803-4	未检出	0.005
133	全氟十三酸	72629-94-8	276-745-2	未检出	0.005
134	全氟十一烷酸	2058-94-8	218-165-4	未检出	0.005
135	全氟十二烷酸	307-55-1	206-203-2	未检出	0.005
136	甲氧基乙酸	625-45-6	210-894-6	未检出	0.005
137	邻苯二甲酸二异戊酯	605-50-5	210-088-4	未检出	0.005
138	N,N-二甲基甲酰胺	68-12-2	200-679-5	未检出	0.005
139	镉 #	7440-43-9	231-152-8	未检出	0.005
140	全氟辛酸铵(APFO)	3825-26-1	223-320-4	未检出	0.005
141	全氟辛酸(PFOA)	335-67-1	206-397-9	未检出	0.005
142	邻苯二甲酸二正戊酯(DPP)	131-18-0	205-017-9	未检出	0.005
143	4-壬基(支链与直链)苯酚乙氧基醚	—	—	未检出	0.005
144	氧化镉 #	1306-19-0	215-146-2	未检出	0.005
145	硫化镉 #	1306-23-6	215-147-8	未检出	0.005



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编号: QHJ2004029701/CH

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发行日期: 2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
146	邻苯二甲酸二己酯	84-75-3	201-559-5	未检出	0.005
147	刚果红 #	573-58-0	209-358-4	未检出	0.005
148	直接黑 38 #	1937-37-7	217-710-3	未检出	0.005
149	1,2-亚乙基硫脲	96-45-7	202-506-9	未检出	0.01
150	醋酸铅	301-04-2	206-104-4	未检出	0.005
151	磷酸三(二甲苯)酯	25155-23-1	246-677-8	未检出	0.01
152	邻苯二甲酸二己酯	68515-50-4	271-093-5	未检出	0.01
153	氯化镉 #	10108-64-2	233-296-7	未检出	0.005
154	水合高硼酸钠盐类 #	—	239-172-9 234-390-0	未检出	0.005
155	过硼酸钠 #	7632-04-4	231-556-4	未检出	0.005
156	2-(2'-羟基-3',5'-二叔丁基苯基)-苯并三唑(UV-320)	3846-71-7	223-346-6	未检出	0.01
157	2-(2H-苯并三唑-2-基)-4,6-二叔戊基苯酚(UV328)	25973-55-1	247-384-8	未检出	0.01
158	二正辛基-双(巯乙酸2-乙基己酯)锡(DOTE)	15571-58-1	239-622-4	未检出	0.01
159	二正辛基-双(巯乙酸2-乙基己酯)锡(DOTE)和三(2-乙基己基巯基乙酸)辛锡(MOTE)的反应产物	—	—	未检出	/
160	氟化镉	7790-79-6	232-222-0	未检出	0.005
161	硫酸镉	10124-36-4 31119-53-6	233-331-6	未检出	0.005
162	1,2-苯二甲酸, 二(C6-10)烷基酯 / 1,2-苯二甲酸, 混合二己二辛二癸酯, 其中邻苯二甲酸二己酯含量≥0.3%	68515-51-5 68648-93-1	271-094-0 272-013-1	未检出	0.01
163	5-二级丁基-2-(2,4-二甲苯环己-3-烯-1-基)-5-甲基-1,3-二恶烷[1], 5-二级丁基-2-(4,6-二甲苯环己-3-烯-1-基)-5-甲基-1,3-二恶烷[2] [任何[1]和[2]或者其任意组合的单独异构体或其任何组合]	—	—	未检出	/



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发行日期: 2020 年 04 月 30 日

No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
164	1,3-丙基磺酸内酯	1120-71-4	214-317-9	未检出	0.01
165	2-(2'-羟基-3',5'-二叔丁基苯基)-5-氯苯并三唑(UV-327)	3864-99-1	223-383-8	未检出	0.01
166	2-(2'-羟基-3'-异丁基-5'-叔丁基苯基)苯并三唑(UV-350)	36437-37-3	253-037-1	未检出	0.01
167	硝基苯	98-95-3	202-716-0	未检出	0.01
168	全氟壬酸及其钠盐和铵盐	375-95-1 21049-39-8 4149-60-4	206-801-3	未检出	0.01
169	苯并(α)芘	50-32-8	200-028-5	未检出	0.01
170	4,4'-异亚丙基二酚(双酚A)	80-05-7	201-245-8	未检出	0.01
171	4-庚基苯酚, 支链和直链	---	---	未检出	0.01
172	全氟癸酸(PFDA)及其钠盐和铵盐	3108-42-7 335-76-2 3830-45-3	206-400-3 221-470-5	未检出	0.01
173	4-叔戊基苯酚(PTAP)	80-46-6	201-280-9	未检出	0.01
174	全氟己基磺酸及其盐类(PFHxS)	---	---	未检出	0.01
175	1,3,4-噻二唑烷-2,5-二硫酮, 甲醛和 4-庚基苯酚的支链和直链(RP-HP)的反应产物[4-庚基苯酚, 支链和直链含量≥0.1%w/w]	---	---	未检出	0.01
176	德克隆[包括所有反式和顺式异构体及其组合]	---	---	未检出	0.01
177	屈	218-01-9 1719-03-5	205-923-4	未检出	0.01
178	硝酸镉	10022-68-1, 10325-94-7	233-710-6	未检出	0.01
179	氢氧化镉	21041-95-2	244-168-5	未检出	0.01
180	碳酸镉	513-78-0	208-168-9	未检出	0.01
181	苯并[a]蒽	56-55-3, 1718-53-2	200-280-6	未检出	0.01
182	苯并(g,h,i)芘(二萘嵌苯)(BPE)	191-24-2	205-883-8	未检出	0.01



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No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
183	十甲基环五硅氧烷 (D5)	541-02-6	208-764-9	未检出	0.01
184	氧化硼钠	12008-41-2	234-541-0	未检出	0.01
185	十二甲基环六硅氧烷(D6)	540-97-6	208-762-8	未检出	0.01
186	乙二胺	107-15-3	203-468-6	未检出	0.01
187	铅	7439-92-1	231-100-4	未检出	0.01
188	八甲基环四硅氧烷(D4)	556-67-2	209-136-7	未检出	0.01
189	氢化三联苯	61788-32-7	262-967-7	未检出	0.01
190	1,2,4-苯三酸酐(偏苯三酸酐)	552-30-7	209-008-0	未检出	0.01
191	邻苯二甲酸二环己酯(DCHP)	84-61-7	201-545-9	未检出	0.01
192	4,4'-(1,3-二甲基亚丁基)二苯酚	6807-17-6	401-720-1	未检出	0.01
193	苯并[k]荧蒽	207-08-9	205-916-6	未检出	0.01
194	荧蒽	206-44-0, 93951-69-0	205-912-4	未检出	0.01
195	菲	85-01-8	201-581-5	未检出	0.01
196	蒽	129-00-0, 1718-52-1	204-927-3	未检出	0.01
197	1,7,7-三甲基-3-(苯基亚甲基)双环[2.2.1]庚-2-酮(3-亚苄基樟脑)	15087-24-8	239-139-9	未检出	0.01
198	三(壬基苯基, 支链和直链)亚磷酸酯 (TNPP), 含 ≥0.1%(w/w)的4-壬基酚, 支链和直链(4-NP)	—	—	未检出	0.01
199	4-叔丁基苯酚	98-54-4	202-679-0	未检出	0.01
200	乙酸2-甲氧基乙酯	110-49-6	203-772-9	未检出	0.01
201	2,3,3,3-四氟-2-(七氟丙氧基)丙酸, 其盐类和酰卤(包括它们各自的异构体及其组合)	—	—	未检出	0.01
202	2-苄基-2-二甲基氨基-1-(4-吗啉苯基)丁酮	119313-12-1	404-360-3	未检出	0.01
203	2-甲基-1-(4-甲硫基苯基)-2-吗啉基-1-丙酮	71868-10-5	400-600-6	未检出	0.01



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No.	测试项目	CAS No.	EC No.	结果 (%)	MDL(%)
204	邻苯二甲酸二异己酯	71850-09-4	276-090-2	未检出	0.01
205	全氟代丁酸及其盐类	—	—	未检出	0.01
206	1-乙烯基咪唑	1072-63-5	214-012-0	未检出	0.01
207	2-甲基咪唑	693-98-1	211-765-7	未检出	0.01
208	对羟基苯甲酸丁酯	94-26-8	202-318-7	未检出	0.01
209	双(乙酰丙酮酸)二丁基锡	22673-19-4	245-152-0	未检出	0.01
210	间苯二酚	108-46-3	203-585-2	未检出	0.01

## 注释:

- MDL = 方法检出限, 所有MDL是基于均一材质的测试。
- 未检出 = 小于方法检出限
- % = 质量百分比
- 测试结果基于测试样品的总质量得出。
- # = 该结果由所选的元素(如锡、砷、铅、钴、六价铬、钼、铝、硅、锆、钠、钾、硼、镉等)的测试结果换算得出。建议客户通过检查化学配方来进一步确认样品中是否存在上述化合物。
- 本报告所列物质来自于欧洲化学品管理署(ECHA)在其官方网站发布的高度关注物授权候选清单, 并利用现有的分析技术完成评估与测试。ECHA 会不定期对该清单进行修改。  
<http://echa.europa.eu/web/guest/candidate-list-table>
- 参考欧盟第1907/2006(EC)号法规第7条第2项的要求, 如果物品中含有授权候选清单中的物质, 且同时满足下列两种情况, 物品的制造商或进口商应参照第7条第4项的内容向欧洲化学品管理署(ECHA)进行通报:(1) 授权候选清单中的某种物质在物品中的含量总合超过1吨/年/生产商或进口商; (2) 授权候选清单中的某种物质在单个物品中的含量以质量分数计超过0.1%。
- 参考欧盟第1907/2006(EC)号法规第33条的要求, 如果物品中含有授权候选清单中的物质, 且该物质的质量分数大于0.1%, 物品的供应商应向物品接受者提供该物质的名称, 以及保证物品安全使用的其他相关信息。
- 如果样品中某种SVHC物质的测试结果超过方法检出限, 建议客户进一步定量检测以得到该SVHC物质的准确浓度。

## 测试方法:

依据实验室内部方法 ZJJC-JC-015A, 采用 ICP-OES、GC-MS、UV-VIS、HPLC-DAD/MS 和比色法分析。

## 测试样品描述:

KN95 防护口罩



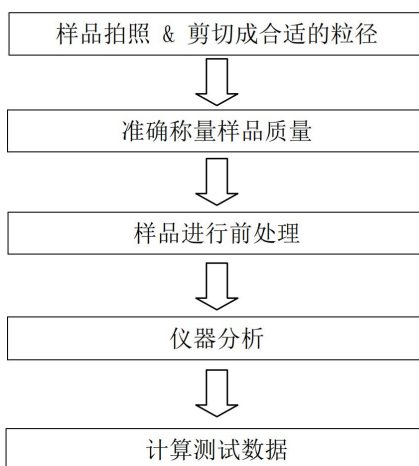
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发行日期: 2020 年 04 月 30 日

测试流程:



附件:



\*\*\*\*\*

所有检测结果只对申请人所送样品负责。本报告部分复制无效。

\*\*\*\*\*报告结束\*\*\*\*\*



**CCIC (Shenzhen) Environmental Service Co., Ltd.**  
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Issued: 2020-04-30

## Test Report

**Applicant** : Dongguan Xianda Medical Equipment Co., Ltd  
**Address** : Room 301, building 7, No. 40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, China

**Manufacturer** : Dongguan Xianda Medical Equipment Co., Ltd  
**Address** : Room 301, building 7, No. 40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, China

**Sample Name** : KN95 protective mask  
**Sample Model** : Folding type  
**Sample Brand** : TOMSON NEWT

**Received Date** : April 26, 2020  
**Testing Period** : April 26, 2020 ~ April 30, 2020

**Test Requested** : As requested by client, SVHC screening is performed according to: two hundred and five (205) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before January 16, 2020 Regarding Regulation (EC) No 1907/2006 concerning the REACH.  
Five (5) substances in the Candidate List of Substances of Very High Concern (SVHC) for consultation on March 3, 2020.

**Test Method** : Please refer to next page.  
**Test Results** : Please refer to next page(s).  
**Conclusion** : According to the specified scope and analytical technique in this report, two hundred and five (205) Substances of Very High Concern (SVHC) concentrations were less than 0.1% (m/m) in the submitted samples.

CCIC (Shenzhen) Environmental Service Co., Ltd.

Completed by:

Suning.Liang

Suning.Liang

Reviewed by:

Andy.Zhou

Andy.Zhou

Approved by:

Renyou.yang

Renyou.yang



## Intermediate inspection REACH test report (English Verision)



**CCIC (Shenzhen) Environmental Service Co., Ltd.**  
Floor 2, Minlida Industrial Park, Honghualing Industrial Zone, Nanshan  
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## Test Results:

No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
1	Cobalt dichloride #	7646-79-9	231-589-4	ND	0.01
2	Diarsenic pentaoxide; #	1303-28-2	215-116-9	ND	0.005
3	Diarsenic trioxide #	1327-53-3	215-481-4	ND	0.005
4	Lead hydrogen arsenate #	7784-40-9	232-064-2	ND	0.005
5	Triethyl arsenate #	15606-95-8	427-700-2	ND	0.005
6	Sodium dichromate, dihydrate #	7789-12-0	234-190-3	ND	0.005
7	Bis (tributyltin) oxide (TBTO) #	56-35-9	200-268-0	ND	0.005
8	Anthracene	120-12-7	204-371-1	ND	0.005
9	4,4-diaminodiphenylmethane (MDA)	101-77-9	202-974-4	ND	0.005
10	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified	25637-99-4 3194-55-6	247-148-4 221-695-9	ND	0.01
	$\alpha$ - HBCDD	134237-50-6	—		
	$\beta$ - HBCDD	134237-51-7	—		
	$\gamma$ - HBCDD	134237-52-8	—		
11	5-tert-butyl-2,4,6-trinitro-mxylene (musk xylene)	81-15-2	201-329-4	ND	0.01
12	Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	204-211-0	ND	0.01
13	Dibutyl phthalate (DBP)	84-74-2	201-557-4	ND	0.005
14	Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	ND	0.005
15	Short chain chlorinated paraffins (C10-13)	85535-84-8	287-476-5	ND	0.005
16	Anthracene oil	90640-80-5	292-602-7	ND	0.01
17	Anthracene oil, anthracene paste, distn. lights	91995-17-4	295-278-5	ND	0.01



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
18	Anthracene oil, anthracene paste, Anthracene fraction	91995-15-2	295-275-9	ND	0.01
19	Anthracene oil, anthracene-low	90640-82-7	292-604-8	ND	0.01
20	Anthracene oil, anthracene paste	90640-81-6	292-603-2	ND	0.01
21	Pitch, coal tar, high temp.	65996-93-2	266-028-2	ND	/
22	2,4-Dinitrotoluene	121-14-2	204-450-0	ND	0.01
23	Diisobutyl phthalate (DIBP)	84-69-5	201-553-2	ND	0.01
24	Lead chromate #	7758-97-6	231-846-0	ND	0.01
25	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) #	12656-85-8	235-759-9	ND	0.01
26	Lead sulphochromate yellow (C.I.Pigment Yellow 34) #	1344-37-2	215-693-7	ND	0.01
27	Tris(2-chloroethyl)phosphate	115-96-8	204-118-5	ND	0.01
28	Acrylamide	79-06-1	201-173-7	ND	0.01
29	Trichloroethylene	79-01-6	201-167-4	ND	0.01
30	Boric acid #	10043-35-3 11113-50-1	233-139-2 234-343-4	ND	0.01
31	Disodium tetraborate, anhydrous #	1303-96-4 1330-43-4 12179-04-3	215-540-4	ND	0.01
32	Tetraboron disodium heptaoxide, hydrate #	12267-73-1	235-541-3	ND	0.01
33	Sodium chromate #	7775-11-3	231-889-5	ND	0.01
34	Potassium chromate #	7789-00-6	232-140-5	ND	0.01
35	Ammonium dichromate #	7789-09-5	232-143-1	ND	0.01
36	Potassium dichromate #	7778-50-9	231-906-6	ND	0.01
37	Cobalt(II) sulphate #	10124-43-3	233-334-2	ND	0.01

## Intermediate inspection REACH test report (English Verision)



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)	
38	Cobalt(II) dinitrate #	10141-05-6	233-402-1	ND	0.01	
39	Cobalt(II) carbonate #	513-79-1	208-169-4	ND	0.01	
40	Cobalt(II) diacetate #	71-48-7	200-755-8	ND	0.01	
41	2-Methoxyethanol	109-86-4	203-713-7	ND	0.01	
42	2-Ethoxyethanol	110-80-5	203-804-1	ND	0.01	
43	Chromium trioxide #	1333-82-0	215-607-8	ND	0.01	
44	Acids generated from chromium trioxide and their oligomers	Chromic acid #	7738-94-5	231-801-5	ND	0.01
		Dichromic acid #	13530-68-2	236-881-5	ND	
		Oligomers of chromic acid and dichromic acid #	—	—	ND	
45	2-ethoxyethyl acetate	111-15-9	203-839-2	ND	0.01	
46	Strontium chromate #	7789-6-2	232-142-6	ND	0.01	
47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	271-084-6	ND	0.01	
48	Hydrazine	7803-57-8 302-01-2	206-114-9	ND	0.01	
49	1-methyl-2-pyrrolidone	872-50-4	212-828-1	ND	0.01	
50	1,2,3-trichloropropane	96-18-4	202-486-1	ND	0.01	
51	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters,C7-rich	71888-89-6	276-158-1	ND	0.01	
52	Dichromium tris(chromate) #	24613-89-6	246-356-2	ND	0.01	
53	Potassium hydroxyoctaoxodizincatedi-chromate #	11103-86-9	234-329-8	ND	0.01	
54	Pentazinc chromate octahydroxide #	49663-84-5	256-418-0	ND	0.01	
55	Aluminosilicate Refractory Ceramic Fibres (RCF) #	—	—	ND	0.05	

## Intermediate inspection REACH test report (English Verision)



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
56	Zirconia Aluminosilicate Refractory Ceramic Fibres #	—	—	ND	0.05
57	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	500-036-1	ND	0.01
58	Bis(2-methoxyethyl) phthalate	117-82-8	204-212-6	ND	0.005
59	2-Methoxyaniline; o-Anisidine	90-04-0	201-963-1	ND	0.005
60	4-(1,1,3,3-tetramethylbutyl)phenol, (4-tert-Octylphenol)	140-66-9	205-426-2	ND	0.005
61	1,2-Dichloroethane	107-06-2	203-458-1	ND	0.005
62	Bis(2-methoxyethyl) ether	111-96-6	203-924-4	ND	0.005
63	Arsenic acid #	7778-39-4	231-901-9	ND	0.01
64	Calcium arsenate #	7778-44-1	231-904-5	ND	0.01
65	Trilead diarsenate #	3687-31-8	222-979-5	ND	0.01
66	N,N-dimethylacetamide	127-19-5	204-826-4	ND	0.005
67	Phenolphthalein	77-09-8	201-004-7	ND	0.005
68	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	202-918-9	ND	0.005
69	Lead azide Lead diazide #	13424-46-9	236-542-1	ND	0.01
70	Lead styphnate #	15245-44-0	239-290-0	ND	0.01
71	Lead dipicrate #	6477-64-1	229-335-2	ND	0.01
72	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	203-977-3	ND	0.005
73	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	203-794-9	ND	0.005
74	Diboron trioxide #	1303-86-2	215-125-8	ND	0.01
75	Formamide	75-12-7	200-842-0	ND	0.01
76	Lead (II) bis (methanesulfonate) #	17570-76-2	401-750-5	ND	0.005



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
77	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinae-2,4,6 -trione(TGIC)	2451-62-9	219-514-3	ND	0.005
78	1,3,5-tris[(2S and 2R)-2-3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione(β-TGIC)	59653-74-6	423-400-0	ND	0.005
79	4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	90-94-8	202-027-5	ND	0.005
80	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	202-959-2	ND	0.005
81	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	208-953-6	ND	0.005
82	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)	2580-56-5	219-943-6	ND	0.005
83	α,α-Bis[4-(dimethylamino)phenyl]-4(phenylamino)naphthalene-1-methanol (C.I.Solvent Blue 4)	6786-83-0	229-851-8	ND	0.005
84	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	209-218-2	ND	0.005
85	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7	ND	0.01
86	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	95-80-7	202-453-1	ND	0.005
87	N-methylacetamide	79-16-3	201-182-6	ND	0.01
88	Pentalead tetraoxide sulphate	12065-90-6	235-067-7	ND	0.005
89	Biphenyl-4-ylamine	92-67-1	202-177-1	ND	0.005
90	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	201-861-7	ND	0.01
91	Dioxobis(stearato)trilead #	12578-12-0	235-702-8	ND	0.005
92	Lead dinitrate #	10099-74-8	233-245-9	ND	0.005
93	Tetralead trioxide sulphate #	12202-17-4	235-380-9	ND	0.005
94	Lead oxide (lead monoxide) #	1317-36-8	215-267-0	ND	0.005



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
95	Lead titanium trioxide #	12060-00-3	235-038-9	ND	0.005
96	4,4'-methylenedi-o-toluidine	838-88-0	212-658-8	ND	0.005
97	Acetic acid, lead salt, basic #	51404-69-4	257-175-3	ND	0.005
98	Dimethyl sulphate	77-78-1	201-058-1	ND	0.01
99	Furan	110-00-9	203-727-3	ND	0.005
100	Pyrochlore, antimony lead yellow #	8012-00-8	232-382-1	ND	0.005
101	Tetraethyllead #	78-00-2	201-075-4	ND	0.005
102	[Phthalato(2-)]dioxotrilead #	69011-06-9	273-688-5	ND	0.005
103	Diethyl sulphate	64-67-5	200-589-6	ND	0.01
104	Lead cyanamate #	20837-86-9	244-073-9	ND	0.005
105	Silicic acid, barium salt, lead-doped #	68784-75-8	272-271-5	ND	0.005
106	Trilead dioxide phosphonate #	12141-20-7	235-252-2	ND	0.005
107	o-Toluidine	95-53-4	202-429-0	ND	0.005
108	o-aminoazotoluene	97-56-3	202-591-2	ND	0.005
109	4-Aminoazobenzene	60-09-03	200-453-6	ND	0.005
110	6-methoxy-m-toluidine (p-cresidine)	120-71-8	204-419-1	ND	0.005
111	Dibutyltin dichloride (DBTC) #	683-18-1	211-670-0	ND	0.001
112	Lead Titanium Zirconium Oxide #	12626-81-2	235-727-4	ND	0.005
113	Methyloxirane (Propylene oxide)	75-56-9	200-879-2	ND	0.01
114	1-bromopropane (n-propyl bromide)	106-94-5	203-445-0	ND	0.005
115	trilead bis(carbonate)dihydroxide #	1319-46-6	215-290-6	ND	0.005

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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
116	Fatty acids, C16-18, lead salts #	91031-62-8	292-966-7	ND	0.005
117	Orange lead( lead tetroxide) #	1314-41-6	215-235-6	ND	0.005
118	Sulfurous acid, lead salt, dibasic #	62229-08-7	263-467-1	ND	0.005
119	4,4'-oxydianiline and its salts	101-80-4	202-977-0	ND	0.01
120	lead oxide sulfate #	12036-76-9	234-853-7	ND	0.005
121	Lead bis(tetrafluoroborate) #	13814-96-6	237-486-0	ND	0.005
122	Silicic acid, lead salt #	11120-22-2	234-363-3	ND	0.005
123	Bis(pentabromophenyl) ether (decabromodiphenyl ether;DecaBDE)	1163-19-5	214-604-9	ND	0.001
124	4-Nonylphenol, branched and linear	—	—	ND	0.01
125	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	204-650-8	ND	0.01
126	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	—	—	ND	0.01
127	1,2-Diethoxyethane	629-14-1	211-076-1	ND	0.01
128	Hexahydromethylphthalic anhydride Hexahydro-4-methylphthalic anhydride Hexahydro-1-methylphthalic anhydride Hexahydro-3-methylphthalic anhydride	25550-51-0 19438-60-9 48122-14-1 57110-29-9	247-094-1 243-072-0 256-356-4 260-566-1	ND	0.01
129	Cyclohexane-1,2-dicarboxylic anhydride; cis-cyclohexane-1,2-dicarboxylic anhydride; trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7 13149-00-3 14166-21-	201-604-9 236-086-3 238-009-9	ND	0.005
130	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	284-032-2	ND	0.005
131	N-pentyl-isopentylphthalate	—	776297-69-9	ND	0.005
132	Heptacosafuorotetradecanoic acid	376-06-7	206-803-4	ND	0.005
133	Pentacosafuorotridecanoic acid	72629-94-8	276-745-2	ND	0.005
134	Henicosafuoroundecanoic acid	2058-94-8	218-165-4	ND	0.005

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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
135	Tricosafuorododecanoic acid	307-55-1	206-203-2	ND	0.005
136	Methoxyacetic acid	625-45-6	210-894-6	ND	0.005
137	Diisopentylphthalate	605-50-5	210-088-4	ND	0.005
138	N,N-dimethylformamide	68-12-2	200-679-5	ND	0.005
139	Cadmium #	7440-43-9	231-152-8	ND	0.005
140	Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	223-320-4	ND	0.005
141	Pentadecafluorooctanoic acid (PFOA)	335-67-1	206-397-9	ND	0.005
142	Dipentyl phthalate (DPP)	131-18-0	205-017-9	ND	0.005
143	4-Nonylphenol, branched and linear, ethoxylated	—	—	ND	0.005
144	Cadmium oxide #	1306-19-0	215-146-2	ND	0.005
145	Cadmium sulphide #	1306-23-6	215-147-8	ND	0.005
146	Dihexyl phthalate	84-75-3	201-559-5	ND	0.005
147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28) #	573-58-0	209-358-4	ND	0.005
148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38) #	1937-37-7	217-710-3	ND	0.005
149	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	202-506-9	ND	0.01
150	Lead di(acetate) #	301-04-2	206-104-4	ND	0.005
151	Trixylyl phosphate	25155-23-1	246-677-8	ND	0.01
152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	271-093-5	ND	0.01
153	Cadmium chloride #	10108-64-2	233-296-7	ND	0.005





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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
154	Sodium perborate; perboric acid, sodium salt #	—	239-172-9; 234-390-0	ND	0.005
155	Sodium peroxometaborate #	7632-04-4	231-556-4	ND	0.005
156	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	223-346-6	ND	0.01
157	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	247-384-8	ND	0.01
158	2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	239-622-4	ND	0.01
159	reaction mass of 2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	—	—	ND	/
160	Cadmium fluoride #	7790-79-6	232-222-0	ND	0.005
161	Cadmium sulphate #	10124-36-4 31119-53-6	233-331-6	ND	0.005
162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5 68648-93-1	271-094-0 272-013-1	ND	0.01
163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	—	—	ND	/
164	1,3-propanesultone	1120-71-4	214-317-9	ND	0.01
165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	223-383-8	ND	0.01
166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	253-037-1	ND	0.01
167	Nitrobenzene	98-95-3	202-716-0	ND	0.01



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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1 21049-39-8 4149-60-4	206-801-3	ND	0.01
169	Benzo[def]Chrysene	50-32-8	200-028-5	ND	0.01
170	4,4'-isopropylidenediphenol(bisphenol A)	80-05-7	201-245-8	ND	0.01
171	4-heptylphenol, branched and linear	—	—	ND	0.01
172	Nonadecafluorodecanoic acid(PFDA) and its sodium and ammonium salts	3830-45-3 3108-42-7 335-76-2	— 221-470-5 206-400-3	ND	0.01
173	p-(1,1-dimethylpropyl)phenol	80-46-6	201-280-9	ND	0.01
174	Perfluorohexane-1-sulphonic acid and its salts(PFHxS)	—	—	ND	0.01
175	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)	—	—	ND	0.01
176	Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus™")	—	—	ND	0.01
177	Chrysene	218-01-9, 1719-03-5	205-923-4	ND	0.01
178	Cadmium nitrate	10022-68-1, 10325-94-7	233-710-6	ND	0.01
179	Cadmium hydroxide	21041-95-2	244-168-5	ND	0.01
180	Cadmium carbonate	513-78-0	208-168-9	ND	0.01
181	Benz[a]anthracene	56-55-3, 1718-53-2	200-280-6	ND	0.01
182	Benzo[ghi]perylene	191-24-2	205-883-8	ND	0.01
183	Decamethylcyclopentasiloxane (D5)	541-02-6	208-764-9	ND	0.01
184	Disodium octaborate	12008-41-2	234-541-0	ND	0.01
185	Dodecamethylcyclohexasiloxane (D6)	540-97-6	208-762-8	ND	0.01

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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
186	Ethylenediamine (EDA)	107-15-3	203-468-6	ND	0.01
187	Lead	7439-92-1	231-100-4	ND	0.01
188	Octamethylcyclotetrasiloxane (D4)	556-67-2	209-136-7	ND	0.01
189	Terphenyl, hydrogenated	61788-32-7	262-967-7	ND	0.01
190	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA)	552-30-7	209-008-0	ND	0.01
191	Dicyclohexyl phthalate (DCHP)	84-61-7	201-545-9	ND	0.01
192	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	401-720-1	ND	0.01
193	Benzo[k]fluoranthene	207-08-9	205-916-6	ND	0.01
194	Fluoranthene	206-44-0, 93951-69-0	205-912-4	ND	0.01
195	Phenanthrene	85-01-8	201-581-5	ND	0.01
196	Pyrene	129-00-0, 1718-52-1	204-927-3	ND	0.01
197	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one	15087-24-8	239-139-9	ND	0.01
198	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq$ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	—	—	ND	0.01
199	4-tert-butylphenol	98-54-4	202-679-0	ND	0.01
200	2-methoxyethyl acetate	110-49-6	203-772-9	ND	0.01
201	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides	—	—	ND	0.01
202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	404-360-3	ND	0.01
203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	400-600-6	ND	0.01
204	Diisohexyl phthalate	71850-09-4	276-090-2	ND	0.01
205	Perfluorobutane sulfonic acid (PFBS) and its salts	—	—	ND	0.01

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No.	Substance name	CAS No.	EC No.	Results (%)	MDL(%)
206	1-vinylimidazole	1072-63-5	214-012-0	ND	0.01
207	2-methylimidazole	693-98-1	211-765-7	ND	0.01
208	Butyl 4-hydroxybenzoate	94-26-8	202-318-7	ND	0.01
209	Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	245-152-0	ND	0.01
210	Resorcinol	108-46-3	203-585-2	ND	0.01

## Note:

1. MDL= Method detection limit. All MDL are based on homogenous material.
2. ND = Not Detected (< MDL)
3. % = Percentage by weight
4. The results shown were calculated based on total weight of all the samples.
5. # =The substance is calculated by using the test results of element (E.g. Tin, Arsenic, Lead, Cobalt, Cr(VI), Molybdenum, Aluminum, Silicon, Zirconium, Sodium, Potassium, Strontium, Boron, Cadmium and so on). The SVHC concentration is based on the assessment of the result and the characteristic of material.
6. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA:  
<http://echa.europa.eu/web/guest/candidate-list-table>  
These lists are under evaluation by ECHA and may subject to change in the future.
7. Reference Regulation (EC) No 1907/2006, paragraph 2 of Article 7, any producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance included in the Candidate List , if both the following conditions are met (a) The substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; (b) The substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).
8. Reference Regulation (EC) No 1907/2006, Article 33, supplier of an article containing a substance included in the Candidate List and the concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.
9. If a SVHC is found over the MDL, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

## Test Method:

In-House method ZJJC-JC-015A, and analyzed by XRF, ICP-OES, GC-MS, UV-VIS or HPLC-DAD/MS.



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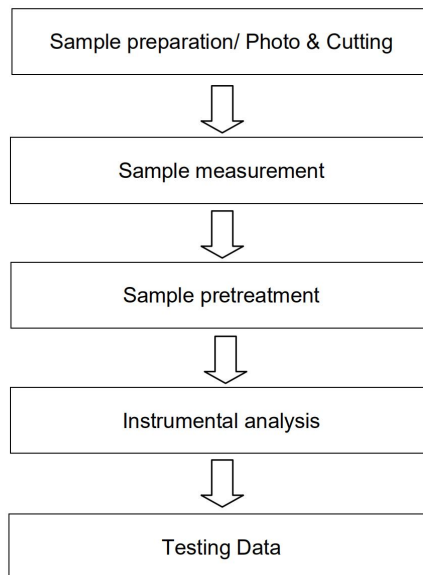
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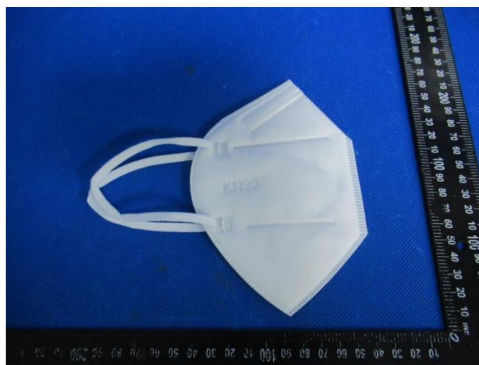
**Test Component Description:**

KN95 protective mask

**Test Process:**



**Appendix:**



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The result of this test report is based on our received samples only.

\*\*\*\*\*End of Report\*\*\*\*\*









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## 口罩展示

Mask display



2层25g 99级熔喷布，5层防护，给你更安心的保护！

2 layers of 25g 99-level meltblown cloth, 5 layers of protection, give you more peace of mind protection!

25克2层99级溶喷



先达医疗5层  
KN95



内嵌鼻梁线，美观且舒适！

Built-in nose bridge line, beautiful and comfortable



## KN95口罩

用于日常环境中普通人群一次性使用卫生护理，用于阻隔飞沫、花粉、微生物等颗粒物传播。



东莞市先达医疗器械有限公司  
Dongguan Xianda Medical Equipment Co., Ltd

产品合格证  
Product Certification

执行标准: GB2626-2006

Standard: \_\_\_\_\_

品名: KN95防护口罩(非医用)  
Product name: KN95 protective mask(Non-medical)

主要成份: 无纺布43.24% + 熔喷布24.33% + 静电滤棉32.43%  
Main Components: Non-woven fabrics 43.24% + Meltblown fabrics 24.33% + Electrostatic filter cotton 32.43%

产品型号: DGXD-325

Model Name: \_\_\_\_\_

产品规格: 15.5cm x 10.5cm

Product specifications: \_\_\_\_\_

数量: 2 PCS

Quantity: \_\_\_\_\_

检验员: \_\_\_\_\_

Inspector: \_\_\_\_\_

生产日期: \_\_\_\_\_

Production date: \_\_\_\_\_

生产批号: \_\_\_\_\_

Production batch: \_\_\_\_\_

保质期: \_\_\_\_\_

Guarantee period: \_\_\_\_\_

厂址: 东莞市石碣镇龙眼路40号7号楼301室

Factory address: Room 301, building 7, No. 40, Longyan Road, Shijie Town, Dongguan City

本产品经检验符合标准要求, 准予出厂  
This product meets the standard after inspection and is allowed to leave the factory

# 18 产品包装图

Product packaging



How to use:  
As shown in the figure:



- 【产品名称】KN95防护口罩
- 【型号名称】DGSD-449
- 【执行标准】GB2626-2006
- 【产品材质】无纺布、熔喷布、热风棉
- 【产品规格】2只/袋

请以最新批次的实物为准



How to use:  
As shown in the figure:



- 【产品名称】KN95 防护口罩
- 【型号名称】DGSD-449
- 【执行标准】GB2626-2006
- 【产品材质】无纺布、熔喷布、热风棉
- 【产品规格】2只/袋



请以最新批次的实物为准

# 纸箱包装图

Carton packaging diagram



- ◆ 【纸箱规格】  
530\*445\*375mm
- ◆ 【净重】 5.1千克
- ◆ 【毛重】 6.1千克
- ◆ 【数量】 600只/箱
- ◆ 【保质期】 2年
- ◆ 【生产日期】 见喷码

请以最新批次的实物为准

# 纸箱包装图

Carton packaging diagram



- ◆ 【品牌】汤臣纽特™
- ◆ 【产品名称】KN95防护口罩
- ◆ 【产品材质】无纺布、熔喷布、静电滤棉
- ◆ 【防护等级】KN95级别
- ◆ 【产品符合新国标】GB2626-2006标准

请以最新批次的实物为准



先达医疗

东莞市先达医疗器械有限公司  
Dongguan Xianda Medical Devices Co., Ltd.