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# KN95 MASK Manufacturer

Production in Dust Free Workshop









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# Certificate

شهادة - Certificat - 증명서 - 證明書 - Сертификат - Certificate

Form QAT\_IG-M04, version 00, effective since March 25th, 2020

## Certificate of Compliance

No. 3P200413.DGLTC45

**Certificate's Holder:** Dong Guan Lucky Tin Co., Ltd.  
North of Xiangxi Industrial Zone, Shipai Town,  
Dongguan City, Guangdong Province

**Certification ECM Mark:** 

**Product Model(s):** Protective Mask  
KN95

**Verification to:** Standard:  
EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

**CE** The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: www.entecerma.it

**Issuance date:** 07 April 2020  
**Expiry date:** 06 April 2025

Reviewer  
Technical expert  
Amanda Payne




Approver  
ECM Service Director  
Luca Bedonni





Ente Certificazione Macchine Srl  
Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY  
☎ +39 051 6705141 📠 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it



Ordering company: Dong Guan Lucky Tin Co. Ltd.  
No. 116, Xiangxi Road, Shipai Town, Dongguan City, Guangdong Province, China

Reply to: DEKRA Testing and Certification GmbH  
Handwerkstraße 15  
70585 Stuttgart  
Germany

**Order**  
We hereby order the items ticked "Yes" according to offer no. Quotation no. PRD/[Kategorie] based on the general terms and conditions of DEKRA Testing and Certification GmbH:

The "Yes" ticked items should be applied according to the section 2.		
Pos. No.	Service	
01	Product Test acc. to Corona rapid test procedure following the harmonized standard EN 149:2001+A1:2009 incl. DEKRA Test Report and issue of a Conformity Verification Document for placing the products on the market and Inverkehrbringen und for passing the market surveillance authorities. Test Specifications: EN 149:2001+A1:2009, Abschnitte 8.3.2 only a, 8.3.1, 8.9.2 und 8.9.3, 8.3.4, 8.11 and optical quality check	<input checked="" type="checkbox"/> Yes

**Disposition of samples after testing:**


Return to customer (costs will be charged on a time and material basis)  Yes

Unless agreed otherwise the samples will be destroyed automatically 4 weeks after finishing the tests.

our value added tax identification number reads: \_\_\_\_\_

Your order no. 807711700  
Date 2020/04/07

Project no. 31767000  
Date 2020/04/07

Legally binding signature / stamp of ordering company: 

DEKRA Testing and Certification GmbH  
Project no. 31767000  
Date 2020/04/07

Legally binding signature / stamp of ordering company: \_\_\_\_\_  
DEKRA Testing and Certification GmbH

Please return to Fax: +49 711 7851-3480 or via e-mail to the contact person mentioned on page 1.

2020

**Notification of New Device Establishment Registration**  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Devices and Radiological Health  
10903 New Hampshire Ave., W066 Room 2621  
Silver Spring, Maryland 20993-0002

April 28, 2020

Name of Official Correspondent	CARRIE LIU
Address of Official Correspondent	NO. 116, XIANGXI ROAD, SHIPAI TOWN DONGGUAN, GUANGDONG 523330 CHINA
Owner Operator Number	10072412

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name	DONG GUAN LUCKY TIN CO. LTD
Establishment Address	NO. 116, XIANGXI ROAD, SHIPAI TOWN DONGGUAN, GUANGDONG 523330 CHINA

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. You will be notified of your official registration number within 90 days.

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.

**ATTACH**

Device Listing	Device#	Code	Device Name
	D397917	MSH	Respirator, surgical (KN95 Respirator, KN95 Mask)
	D397914	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance (Protective mask)

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# 4 Certificate

Total Quality. Assured.

## CERTIFICATE OF REGISTRATION

Intertek Certification Ltd (UKAS 014) certifies that, having conducted an audit for the scope of activities: Cutting, punching/forming and packing of tin boxes for use in direct contact with dry food

Exclusions from Scope: Tin boxes for the gift and stationery in the workshop for non-food contact product

Fields of Audit: 03

Hygiene Category: High hygiene, at

**Dong Guan Lucky Tin Co., Ltd**  
 BRC Site Code: 1784149

Site Address: North of Xiangxi Road Industrial Zone, Shipai Town, Dongguan City, Guangdong Province, 523330, P. R. China

**Has achieved Grade: B**

Meets the requirements set out in the

**BRC GLOBAL STANDARD for PACKAGING AND PACKAGING MATERIALS**  
**ISSUE 5: JULY 2015**

Audit Programme: Announced

**BRC**  
 Certification Body  
 CERTIFICATED

**Auditor Number:**  
168220

**Certificate Number:**  
05181911001

**Dates of Audit:**  
18-19 Nov 2019

**Certificate Issue Date:**  
10 Jan 2020

**Re-audit Due Date:**  
From 10 Nov 2020  
To 08 Dec 2020

**Certificate Expiry Date:**  
19 Jan 2021

**Intertek**

**Calin Moldovean**  
 President Business Assurance

Intertek Certification Ltd – 10a Victory Park,  
 Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a  
 UKAS accredited body under  
 schedule of Accreditation No. 014

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's BRC Regulations. The certificate remains the property of Intertek, to whom it must be returned upon request. Validity may be confirmed via email at [certification@intertek.com](mailto:certification@intertek.com) or by scanning the code to the right with a smartphone. If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC please contact [enquiries@brc.com](mailto:enquiries@brc.com) or call the Toll BRC Hot line +44 (0)20 7717 5959. Visit the BRC Directory ([www.brcdirectory.com](http://www.brcdirectory.com)) to validate the authenticity of this certificate

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Total Quality. Assured.

## LETTER OF COMPLIANCE NO. LOC-SZ1910A1

This is to prove:

**Dong Guan Lucky Tin Co., Ltd.**

Xiangxi Road North Industrial Zone, Shipai Town, Dongguan City, Guangdong Province ,China

has been assessed by Intertek as conforming to the requirements of:

**ISO15378:2017 PRIMARY PACKAGING MATERIALS FOR MEDICINAL PRODUCTS – GOOD MANUFACTURING PRACTICE (GMP)**

The scope of activities:  
 Manufacturing of tin cans for band-aids

**Initial Audit Date:**  
 08-10 Sept, 2019

This Letter Of Compliance is valid from 14 Oct, 2019 to 13 Oct, 2020.

**Helen Xue**  
 Vice President  
 Life & Environment Science

The approval is subject to the organization maintaining the system in accordance with Intertek's relevant rules and regulations. For current status and details of the assessment result, please contact us: [hbp.scadmin@intertek.com](mailto:hbp.scadmin@intertek.com).

# 5 Certificate



**SMETA** Sedex Audit Reference: 2019CNZAA407056165/ 2019CNZAA407795086  
Sedex Members Ethical Trade Audit Report Version 6.0

Audit Details			
Sedex Company Reference: (only available on Sedex System)	ZC:1015087	Sedex Site Reference: (only available on Sedex System)	ZS:1013742
Business name (Company name):	Dong Guan Lucky Tin Co. Ltd		
Site name:	Dong Guan Lucky Tin Co. Ltd 东莞市乐天制罐有限公司		
Site address: (Please include full address)	North of Xiangxi Road Industrial Zone, Shipai Town, Dongguan City, Guangdong Province, China 中国广东省东莞市石排镇向西大道北工业区	Country:	China
Site contact and job title:	Ms. Huang Youfeng /HR Supervisor		
Site phone:	86-769-81829878	Site e-mail:	he@tinworld.cn
SMETA Audit Pillars:	<input checked="" type="checkbox"/> Labour Standards	<input checked="" type="checkbox"/> Health & Safety	<input checked="" type="checkbox"/> Environment <input checked="" type="checkbox"/> Business Ethics
Date of Audit:	2 <sup>nd</sup> September 2019		
<b>Audit Company Name &amp; Logo:</b>  		<b>Report Owner (payee):</b> <i>(If paid for by the customer of the site please remove for Sedex upload)</i>  Dong Guan Lucky Tin Co. Ltd	
Audit Conducted By			
Affiliate Audit Company	<input checked="" type="checkbox"/>	Purchaser	<input type="checkbox"/>
Brand owner	<input type="checkbox"/>	NGO	<input type="checkbox"/>
Multi-stakeholder	<input type="checkbox"/>	Trade Union	<input type="checkbox"/>
Multi-stakeholder <input type="checkbox"/> Combined Audit (select all that apply)			

Audit company: Intertek Report reference: A4790775 Date: 2nd September 2019 Sedexglobal.com 2

**GTT** **MA** **Doc-MRA** **CNAS**  
1.740001.12982

## 检验检测报告

委托单位			
样品信息	KN95防护口罩		
检验性质	样品受理/测试开始日期	报告签发日期	
判定依据	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
综合检验结论	---		
检验检测结果	检验检测项目	判定依据	判定
备注			

# 6 Product Instruction



Product: KN95 MASK  
 Specification: 16\*10.7cm,5 layers/LT-M01  
 Main Material: Non-woven fabric 72%  
 Melt-blown fabric 28%

Standard: GB2626-2006  
 Batch No.: 0428  
 Production Date: 2020/4/28  
 Valid For: 3 Years  
 Inspector:



# 7 Product Picture



## KN95 MASK



# 8 Packing Details



**LUCK**

**How to wear**

1. With the nose dip facing away from you, hold the ear straps with both hands. Make sure the nose clip is facing up.
2. Position the respirator so that it covers your nose and chin. Fasten the elastic straps behind your ears.
3. Place the fingertips of both hands at the top of the metal nose clip. Mold the nose clip to the shape of your nose bridge by pushing inwards while moving your fingertips down both sides of the nose dip.
4. Conduct an air tightness inspection to make sure the mask is sealed against your face.

**Model No:** LT-M01  
**Executive Standard:** KN95/GB 2626-2006;  
 Non Medical Standard

**WARNING**

This respirator helps protect against certain particles. It does not eliminate the risk of disease or infection. Misuse can result in sickness or death. Materials in direct contact with the skin may cause allergic reactions in some sensitive individuals.

**20 pcs**

**Model No:** LT-M01  
**Executive Standard:** KN95/GB 2626-2006;  
 Non Medical Standard

**LUCK**

**KN95 MASK**

**WARNING**

This respirator helps protect against certain particles. It does not eliminate the risk of disease or infection. Misuse can result in sickness or death. Materials in direct contact with the skin may cause allergic reactions in some sensitive individuals.

**Manufacturer:** Dong Guan Lucky Tin Co. Ltd  
**Address:** No.116,Xiangxi Road,ShipaiTown, Dongguan,Guangdong,China  
**Tel:** +86 769 8652 8008





# 9 Packing Details

MODEL: LT-M01  
QTY: 960PCS/CTN  
SIZE: 54.5x34x48CM  
NW.: 7.0 KG  
GW.: 8.5 KG

