

Certificate FI20/967675

Cangnan County Jiawei Bag Making Factory

No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425

Module B, EU type-examination

This certificate is valid from 15 December 2020 until 15 December 2025 CERTIFICATE IS VALID FOR THE PROPERTY OF THE PROPERTY

> Authorised by Second Second

Finnish Accreditation Service S003 (EN ISO/IEC 17065)

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Certificate CN20/42715

The management system of

Cangnan County Jiawei Bag Making Factory

No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

For the following activities

Manufacture of JW (logo) CNJW-2020 particle filtering half mask. (Note: All products marked CE0598 must have a valid EU typeexamination certificate issued under Module B or a valid EC typeexamination certificate issued under Article 10 of Directive 89/686/EEC.)

> This certificate is valid from 22 December 2020 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 22 December 2020

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尊敬的客户: Dear Client,

我们很高兴通知您,贵司的证书已经颁发。证书的电子版本请见附件,纸质原件已寄送。 We are glad to inform you that, your certificate has finally issued. Attached is the e-copy of the certificate, while the paper certificate is delivered by express.

根据 PPER 法规第 16、17 条款对于 CE mark 的使用说明,您现在可以在产品及包装上使用 CE 0598 标识。

According to the PPER Article 16, 17 which are the instruction of CE mark use. You can have CE marked on your product and package.

作为制造商,根据 PPER 法规要求,您取得 C2 证书后 6 个月内需开始生产并接受现场审核或转 module D 证审核,否则 C2 证书会暂停直至失效。

As a legal manufacture, according to the requirement of PPER, you should accept the first on site audit within 6 months of issue of the C2 certificate (following issue of the first Module B certificate). If production has not started during the 6 months, the certificate should be suspended.

最后,我们借此机会衷心祝贺您的产品获得认证,并期待于贵司保持长期和成功的合作关系。 Finally, we would like to take this opportunity to congratulate you on your product certification and look forward to your long-term and successful cooperation.

通标标准技术服务有限公司 SGS CSTC Standards Technical Services Co., Ltd. 个人防护认证团队 PPE Certification Team 2020 年 11 月



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Certificate FI20/967675, continued

Cangnan County Jiawei Bag Making Factory

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

JW (logo) CNJW-2020 particle filtering half mask, consisting of a white five layer (polypropylene/ polypropylene/ polypropylene / polypropylene) disposable face mask, with nose clip and nylon/ spandex ear loop.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production

> Certification is based on technical file reference: Face mask / CNJW-2020, version1, dated: 2020-10-20.

> > SGS Reference Number UK/CRS 242444.

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Certificate FI20/967675

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Certificate FI20/967675, continued

Cangnan County Jiawei Bag Making Factory

Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

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Cangnan County Jiawei Bag Making Factory

Regulation (EU) 2016/425

Module B, EU type-examination

Issue 1

PPE Product

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中国认可 国际互认 检测 TESTING CNAS L0599

Test Report

SL52035297133901TX

Date:September 02,2020

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Sara Guo (Account Executive)



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Date:September 02,2020

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Test Result





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End of Report



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Section 9

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Cangnan County Jiawei Bag Making Factory

Address: No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

declares that the new PPE described hereafter

Description of products	Face mask
Product style/order No	CNJW-2020
Product colour and type	White, Non-reusable, folded, particle filtering half mask

are in conformity with the Regulation (EU) 2016/425 and with harmonized standard

EN 149:2001 + A1:2009

SGS Fimko Oy

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

performed the EU type-examination (Module B) and issued the EU type-examination certificate FI????

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SGS Fimko Oy, Notified Body No. 0598.

Signed for on behalf of Company

Name: Yankun Xiang Position: General manager Signature: YJNKUNXIJN9 Date: 10/20/2020





YAFOX respirátor triedy FFP2 v bielej farbe.



Príloha č. 2 - Návrh na plnenie kritérií

Identifikačné údaje:

Názov zákazky: "Výzva č. 2 - Respirátor FFP2 bez výdychového ventilu"

Uchádzač:	Remaplast spol. s.r.o.	
Adresa sídla:	Kopčianska 15	
IČO:	31325017	
Číslo účtu (IBAN):		
Telefónne číslo:	+	
E-mailová adresa:	stredisko-ba@remaplast.sk	

Ponuková cena v súlade s opisom predmetu zákazky:

Názov	Celková cena v eur s DPH
Respirátor FFP2 bez výdychového ventilu v celkovom množstve 120 000 ks	13 200 €

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky. Verejný obstarávateľ upozorňuje, že novelou 67/2020 Z. z. účinnou od 12.02.2021 sa na respirátory FFP3 a FFP2 zaviedla 0 (nulová) DPH. Na základe uvedeného **bude celková cena s DPH totožná s celkovou cenou bez DPH a to bez ohľadu na to, či uchádzač je alebo nie platiteľom DPH.**

Čestné vyhlásenie: Predložením tejto ponuky zároveň čestne vyhlasujem, že postupujem v súlade s etickým kódexom uchádzača vydaným Úradom pre verejné obstarávanie:

https://www.uvo.gov.sk/zaujemcauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html

V Bratislave dňa 26.05.2021



pečiatka a podpis osoby oprávnenej konať za uchádzača Page 1 of 17

Documentation No.: Face mask / CNJW-2020 Creation Date: 2020-12-14 Revision No.: Version 2 Revision Date: /

Technical File to comply with the requirements of the Personal Protective Equipment Regulation (EU) 2016/425

Respiratory protective devices - Filtering half masks to protect against particles

EN 149:2001 +A1:2009

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Section 1

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- 5 <u>Essential Health and Safety Requirements</u>
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- 8 <u>Test Reports</u>
- 9 Declaration of Conformity
- 10 Declaration of Material Innocuousness

Section 2

Applicant/Manufacture & Product General Information





Product Details



3. Parts List



4. Product(s) Dimension



Nosepiece: L=82mm±5mm, W=5mm±0.5mm

Section 4

Manufacture Information

2. Qualit Control Procedure

Section 5

Essential Health and Safety Requirements

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Essential Health and Safety Requirements of	Clause of EN149:2001+A1:2009
	And

Essential Health and Safety Requirements of Regulation (EU) 2016/425, Annex II	Clause of EN149:2001+A1:2009
	And
	Section of this Technical File

Section 6

Instruction for use

EXPLANATION OF MARKING



EASY TO USE/DONNING AND FITTING






EN 149:2001+A1:2009

Section 9

EU DECLARATION OF CONFORMITY



Signed for on behalf of Company

Name: Yankun Xiang Position: General manager Signature: YJNKUN XiJN9 Date: 10/20/2020

Section 10

DECLARATION OF MATERIAL INNOCUOUSNESS

The manufacturer or his authorized representative established in the Community:

Manufacturer: Cangnan County Jiawei Bag Making Factory

Address: No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

declares that the materials which are coming into contact with the human skin and body used on the new PPE described hereafter

Product description:

Description of products	Face mask
Product style/order No	CNJW-2020
Product colour and type	White, Non-reusable, folded, particle filtering half mask

are known not to undergo appreciable alteration from contact with sweat or with substances likely to be found in toiletries and are known not to cause any harm to human skin and body.

Done at No.39-40, Xiangdong Village, Qian Ku Town, Cangnan County, Wenzhou City, Zhejiang Province, China

Signed for on behalf of Company Name: Yankun Xiang Position: General manager Signature: Date: 10/20/2020





NO.285 WENGJIAO ROAD, HAICANG DISTRICT, XIAMEN, FUJIAN, CHINA

EU DECLARATION OF CONFORMITY



We,

Manufacturer: ZAIDTEK ELECTRONIC TECHNOLOGY (XIAMEN)CO., LTD.

Address: NO.285 WENGJIAO ROAD, HAICANG DISTRICT, XIAMEN, FUJIAN, CHINA

Declare on our own responsibily, that the:

Product Name: Particle filtering half mask

Model name: HKN001

Are in compliance with following Regulation/directive:

Reg. EU/2016/425 Personal Protective Equipment . Cat. III

and are in compliance with following harmonized standard:

|--|

Identical Products were certified by Notified Body for PPE Module B+C2:

Notified Body No: 2163 Certificate No: 2163-PPE-1364/01 UNIVERSAL SERTIFIKASYON VE GOZETIM HIZM.TIC.LTD.STI. Keyap Ticaret Merkezi,Necip Fazil Bulvan, E2 Blok, No:44/84 Y. Dudullu-Umraniye-ISATANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

This document is related the product: YAFOX HKN001 filtering half mask FFP2

Michael Lan

Authorized Representative:

Date: Nov.10.2020

Zaidtek Electronic Technology (Xlamen) Co., Ltd. No. 285, Wengjiao Road, Xinyang Street, Haicang District, Xiamen, Fujian



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1364

Respiratory protective devices, filtering half masks to protect against particles manufactured by Zaidtek Electronic Technology (Xiamen) Co., Ltd. No. 285 Wengjiao Road, Haicang District, Xiamen, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices -Filtering Half Masks to Protect Against Particles -Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model: HKN001 Filtering half mask Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 27/08/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ UNIVERSAL CERTIFICATION Director





TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 27.08.2020 / 2163-KKD-1364







ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT











Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive













