Inhaltsverzeichnis Zertifikate / Prüfberichte
Ordner EMIX Trading AG, *Stand 01.02.2022*

4.1	**Angtai KN95**
4.2	**Chemipharma**
4.3	**Gaidien 3 Ply**
4.4	**Guanhua KN95**
4.5	**Naisian KN95**
4.6	**Pinyue KN95**
4.7	**SWORD 3 PLY**
4.8	**Teyin FFP2**
4.9	**YI Cheng KN95**
4.10	**Yeufon 3 Ply**
4.11	**Yeufon KN95**

EC Declaration of Conformity

Manufacturer:

Zhuhai Huashi Medical Devices Co., Ltd

Room 203, 2nd Floor, Building 1, No. 1, Huaguan Road,
Tangjiawan Town, High-tech Zone, Zhuhai City,
Guangdong Province, China

whose single Authorized EU-Representative:

CMC MEDICAL DEVICES & DRUGS S.L.
C/ Horacio Lengo No 18, CP 29006,
Málaga, Spain
Tel: +34 951 214 054
E-mail: info@cmcmedicaldevices.com

We, the manufacturer, herewith declare that the products

Disposable medical face mask

17.5cm×9.5cm

Type IIR

Applied Standard: EN 14683:2019+AC:2019

Test report:1302428-S01，1302438-S01，1302439-S01

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Zhuhai Huashi Medical Devices Co., Ltd

Room 203, 2nd Floor, Building 1, No. 1, Huaguan Road,
Tangjiawan Town, High-tech Zone, Zhuhai City, Guangdong Province, China

Zhuhai 2020.10.15
Place, date

Legally binding signature, Function

Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

CE Documentation Review

No. 0P200310.ZHM0O16

Holder:	Zhuhai Huashi Medical Devices Co., Ltd. Room 203 Building 1, No.1 Huaguan Road, Tangjiawan Town, High-tech Zone, Zhuhai 519085 China.
Review goal:	Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII
Product:	Disposable medical mask (no sterile)
Model(s):	HS-P001
Classification:	Class I (no sterile) (accordingly to the Manufacturer's declaration)
Review output:	We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. TMGD20030922018. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 11 March 2020

Chief Manager
Marco Morino

Expiry date 09 March 2025

Deputy Manager
Amanda Fayne

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Technical Construction File
EN 14683: 2019
Medical face masks - Requirements and test methods

Report reference No.....:	TMGD20030922018
Compiled by (+ signature).....:	Stephen Zhang / Test Engineer
Approved by (+ signature).....:	Kosco Vent / Project Manager
Date of issue.....:	March 11,2020
Reviewing laboratory.....:	Shanghai Global Testing Services Co., Ltd.
Reviewing location.....:	Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Applicant.....:	Zhuhai Huashi Medical Devices CO., Ltd.
Address.....:	Room 203 Building 1, No.1 Huaguan Road, Tangjiawan Town, High-tech Zone, Zhuhai 519085 China
Manufacturer.....:	Zhuhai Huashi Medical Devices CO., Ltd.
Address.....:	Room 203 Building 1, No.1 Huaguan Road, Tangjiawan Town, High-tech Zone, Zhuhai 519085 China
Factory.....:	The same as applicant
Address.....:	
Standard.....:	☒ EN 14683: 2019
Review Report Form No.....:	14683
TRF originator.....:	GTS
Master TRF.....:	Reference No. EN 14683: 2019
Review procedure .....:	GTS
Type of Review object.....:	Disposable medical mask
Trademark.....:	-
Main Model.....:	HS-P001
Other Models.....:	/
Rating.....:	/

GLOBAL TESTING SERVICES CO., LTD. CERTIFICATION

Possible review case verdicts: - review case does not apply to the test object.....: N(.A.) - review object does meet the requirement.....: P(ass) - review object does not meet the requirement.....: F(ail)
General remarks:
"(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. The review results presented in this report relate only to the object reviewed. This report shall not be reproduced except in full without the written approval of the third party.

Testing:	
Date of receipt of review item:	March 2, 2020
Date(s) of performance of review:	March 2,2020 to March 11,2020

General product information: Disposable medical mask
Summary of reviewing: This review report includes: Annex I: 2 page(s) of photo documentation.
Copy of marking plate

Disposable medical mask, Model HS-P001 Zhuhai Huashi Medical Devices CO., Ltd.	Marking 

4	Classification		--
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type II R	P
5	Requirements		--
5.1	General		--
5.1.1	Materials and construction		--
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	Design		--
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		--
5.2.1	General		--
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)		--
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.	BFE ≥ 98	P
5.2.3	Breathability		--

	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		P
5.2.4	Splash resistance		--
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden)		--
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1). To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018 may be applied. In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.		--
5.2.6	Biocompatibility		--
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		P
5.2.7	Summary of performance requirements		--

	Table 1 — Performance requirements for medical face masks [3] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.	Type IIR BFE≥98 Differential pressure <49.0 Splash resistance pressure ≥16 Microbial cleanliness ≤30	P
6	Marking, labelling and packaging		--
	Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, § 23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied: a) number of this European Standard; b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

Test	Type I [3]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

- End of Review Report -

Type of equipment, model: Disposable medical mask, HS-P001

Details of:

View:

[X] general

[ ] front

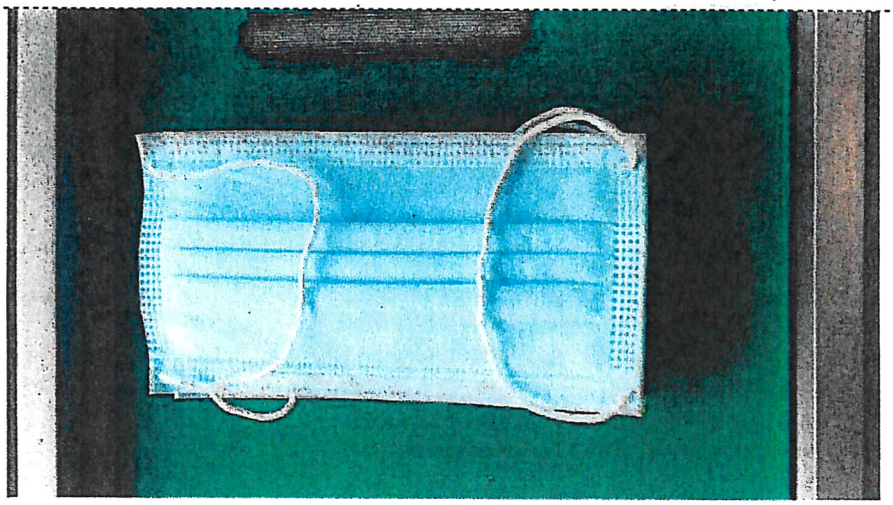
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Details of:

View:

[X] general

[ ] front

[ ] rear

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[ ] left

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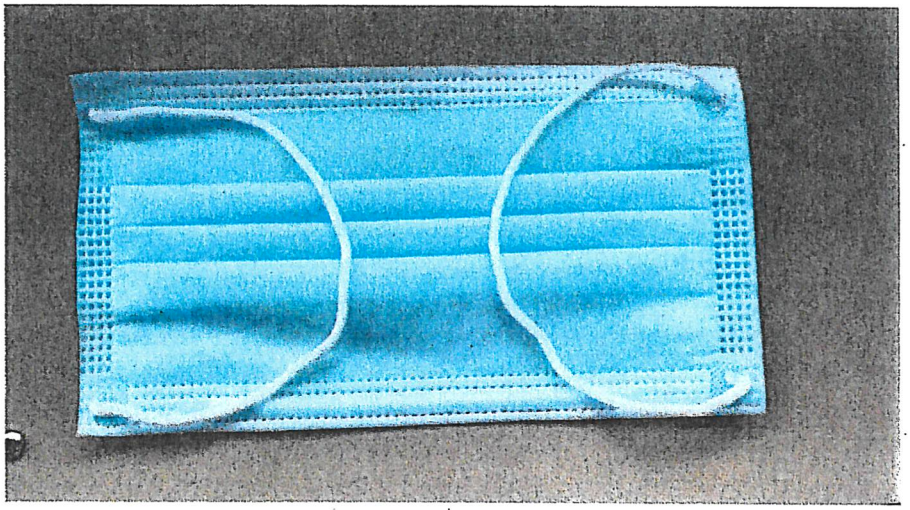


- End of Annex I -

珠海市市场监督管理局

关于珠海华实医疗器械有限公司申请第二类医疗器械应急审批的情况说明

珠海华实医疗器械有限公司为我市生产企业，成立于2020年，位于珠海市高新区唐家湾镇华冠路1号1栋第二层厂房203室，法人代表：曹海霞。该企业现有拟用于本次申请品种实际生产面积600㎡，员工50人，主要生产一次性医用口罩、医用外科口罩、医用防护口罩等产品。为满足新冠肺炎疫情防控物资保障所需，该企业申请一次性医用口罩、医用外科口罩、医用防护口罩产品进入应急审批程序，有关情况如下：

一、拟申请产品名称：

（一）一次性使用医用口罩，结构组成：无纺布、熔喷布、口罩带和可塑性材料制成，适用范围：适用于使用者在无液体或喷溅风险的普通医疗环境下的卫生护理和公共卫生场所中的一般卫生护理，执行标准：YY0969-2013。属于当前疫情防控急需物资。

（二）医用外科口罩，结构组成：无纺布、熔喷布、口罩带和可塑性材料制成，适用范围：适用于临床医务人员在有创

过程中佩戴，为医务人员提供防止血液、微生物、体液和颗粒物等直接透过的物理屏障，执行标准：YY0469-2011。属于当前疫情防控急需物资。

（三）医用防护口罩，结构组成：无纺布、熔喷布、口罩带和可塑性材料制成，适用范围：可用于医疗救护、卫生防疫和现场处置人员处置传染病疫情或突发事件中防止空气微生物和颗粒物的吸入，执行标准：GB19083-2010。属于当前疫情防控急需物资。

二、该产品的主要生产设备已经安装到位，主要原材料已订购；投产后，日产能30万个/天。

三、当前，申请产品及其同类产品市场供应不足，在疫情防控期间确需应急采购。

特此说明。

珠海市市场监督管理局

2020年3月10日

统一社会信用代码
91440407MA54BU4L9L

营业执照

（副　本）（副本号:1-1）

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　珠海华实医疗器械有限公司

商事主体类型　有限责任公司（非自然人投资或控股的法人独资）

法定代表人　曹海霞

成立日期　2020年02月26日

住　　所　珠海市高新区唐家湾镇华冠路1号1栋第二层厂房203室

重要提示

1.经营范围：商事主体的经营范围在章程中载明（其中合伙企业的经营范围在合伙协议中载明，个人独资企业和个体工商户的经营范围在设立登记申请书中载明）。经营范围中属于法律、法规规定应当经批准的项目，在依法取得许可审批后方可从事该经营活动。

2.年度报告：外商投资企业应于每年1月1日至6月30日、其他商事主体应于每年的成立周年之日起两个月内提交上一年年度报告。

3.信息查询：商事主体经营范围、出资情况、营业期限、许可审批项目等有关事项和其他监管信息，请登录珠海市商事主体登记许可及信用信息公示平台（网址：http://ssgs.zhuhai.gov.cn）、国家企业信用信息公示系统或扫描执照上的二维码查询。

登记机关　珠海市市场监督管理局

2020 年 02 月 26 日

对外贸易经营者备案登记表

备案登记表编号：04831687　　统一社会信用代码：91440407MA54BU4L9L

进出口企业代码：

经营者中文名称	珠海华实医疗器械有限公司		
经营者英文名称	ZHUHAI HUASHI MEDICAL DEVIES 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	珠海市高新区唐家湾镇华冠路1号1栋第二层厂房203室		
经营场所（中文）	珠海市高新区唐家湾镇华冠路1号1栋第二层厂房203室		
经营场所（英文）	Room 203 Building 1,No.1 Huaguan Road,Tangjiawan Town,High-tech Zone,Zhuhai 519085 China		
联系电话	0756-3398019	联系传真	0756-3398001
邮政编码	519085	电子邮箱	higrand@163.com
工商登记注册日期	2020-2-26	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	曹海霞	有效证件号	430104197202162124
注册资金	伍佰万元		（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负责人签字、盖章。

备案登记机关

签章

2020 年 08 月 19 日

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

2020年 3 月 20 日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。

海关进出口货物收发货人备案回执

企业名称	珠海华实医疗器械有限公司
统一社会信用代码	91440407MA54BU4L9L
海关备案日期	2020-03-20
海关编码	440436001M
检验检疫备案号	4859500173
有效期	长期

2020年3月20日

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。

DMT - Prüf- und Ergebnisprotokoll

Prüfung Corona SARS-Cov-2-Virus Pandemie Atemschutzmasken

in Anlehnung an Prüfgrundsatz Rev. 1 vom 26.03.2020 - erstellt von der DEKRA Testing and Certification GmbH und dem Institut für Arbeitsschutz (IFA) der Deutschen gesetzlichen Unfallversicherung)

Allgemeines

Berichts Nr.:	Prüfzeitraum:	Datum Prüflingsannahme:
800 301 7908 -38	11.04.2020	09.04.2020

Prüfung beauftragt durch:	Hersteller:	Unterschrift Prüfer:	Unterschrift Leiter Prüfeinheit:
TÜV NORD CERT GmbH & Co. KG Langemarckstraße 20 45141 Essen Deutschland	Zhuhai Hiashii Medical devices Co. Ltd.	11.04.2020 (Glätzer)	11.04.2020 (Schamberg)

Angaben zum Prüfling (Prüfmuster)

Modell/Typbezeichnung (*):	Atemschutzmaske mit Nasenbügel
Schutmaskenart:	FFP
Hersteller:	Zhuhai Hiashii Medical devices Co. Ltd.
Modellbezeichnung:	Yeufon FFP2 Face Mask
Ident.-Nr./Artikelnummer:	AVIS-Nr. 738

Lieferumfang

Verpackungsart:	Karton
Verpackungseinheit:	50 Masken pro Verpackung
Informationsbroschüre:	nicht vorhanden

Prüfungen und Test-Ergebnisse

1. Sichtprüfung

Kriterium	Bewertung
Verpackungsart:	Karton
Verpackungseinheit:	50 Masken pro Verpackung
Verpackung stoßsicher:	stoßsicher
Verpackung staubdicht:	staubdicht
Zustand CPA:	i.o.
Beurteilung:	bestanden

2. Anlegeprüfung

Kriterium	Bewertung
CPA leicht anzulegen	ja
CPA leicht abzulegen	ja
Komfort der Kopfbänderung	teilweise zu locker (Bänder nur aufgeklebt)
Gesichtsfeld	teilweise eingeschränkt
offensichtliche Undichtigkeiten:	nein
Wahrnehmbare Luftströmung:	nein
Beurteilung:	bestanden

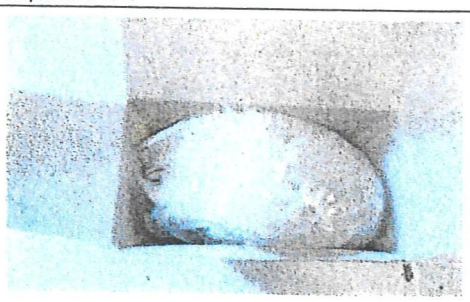
3. Prüfung des Atemwiderstandes CPA

Ausatemwiderstand bei 160 l/min - Sollwert < 300 Pa		
Blickrichtung:	**Druckverlust**	**Beurteilung**
gerade aus	241 Pa	**bestanden**
Einatemwiderstand bei 95 l/min - Sollwert < 240 Pa		
gerade aus	190 Pa	**bestanden**
Einatemwiderstand bei 30 l/min - Sollwert < 70 Pa		
gerade aus	< 63 Pa	**bestanden**

4. Durchlass-Prüfung (Mittelwert Prüflinge 1-3)

Aerosol-Konzentration nach Maske - Reingas C_2 [mg/m³]:	0,0
Aerosol-Konzentration vor Filter - Rohgas C_1 [mg/m³]:	4,6
Durchlassgrad P [%]:	0,9
Sollwertabgleich:	P1-2 ≤ 6%
Beurteilung:	bestanden

Abbildungen der verpackten CPA



Gesamtbeurteilung der geprüften Schutzmaske: **bestanden**

DMT GmbH & Co. KG
Am TÜV 1
45307 Essen / Germany
TÜV NORD GROUP