File No: CE/MDR-EEXI-01-02 Ver: A

Declaration of Conformity

Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Hunan EEXI Technology&Service Co., Ltd.

Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

European Authorised Representative

Name: SUNGO Europe B.V.

Address：Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Medical Face Mask

Model: Flat-type: YX005 14.5*9.0cm

SRN: -

UDI-DI: -

Classification: I

Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (2017/745)

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012
EN ISO 15223-1: 2016
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 1041: 2008
EN 14683:2019+AC: 2019 Type I

Signature:

Robbin Liu

Gerneral Manager

Il/La sottoscritto/a Sante Di Renzo, per conto di SANTE DI RENZO,
avente giusta delega da parte del Fabbricante o del Mandatario per l'inserimento dei dati
dei dispositivi medici sotto riportati, convalida in data 16/09/2020 le seguenti informazioni:
****
****
Progressivo di Sistema:1994899
Nome commerciale e modello: DISPOSABLE MEDICAL FACE MASK
Codice attribuito dal fabbricante (identificativo catalogo): YX005
Ruolo dell''utente che ha inserito il DM: ALTRO SOGGETTO DELEGATO DAL FABBRICANTE
Fabbricante: HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD.
Mandatario: SUNGO EUROPE B.V.
Classificazione CND: MASCHERINE CHIRURGICHE STANDARD
Nomenclatore GMDN completo: GMDN non dichiarato
Classificazione CE: Classe I non sterile e senza funzioni di misura
Allegati secondo cui è stato marcato il dispositivo: Allegato VII
Legame con altri DM: No

Documentazione Allegato
Etichetta:TIPO 1 BAMBINI (YX005) label.pdf
Istruzioni per l'uso:TIPO 1 BAMBINI (YX005)INSTRUCTION PAPER.pdf
---
Dati Tecnici
Misura (ove applicabile): 14,5 x 9 cm
Presenza Tessuti/Sostanze: No
Presenza Medicinali: No
I materiali prevalenti costituenti il confezionamento primario del DM necessitano di condizioni speciali di smaltimento: No
Sterile: No
Monouso: Si
Latex - durante il processo di lavorazione il prodotto è venuto a contatto con molecole di lattice: No
Latex - il prodotto e il suo confenzionamento sono privi di lattice: Si
Materiali costituenti il DM a diretto contatto con il Paziente
Materiale: FIBRE
Materiale: POLIPROPILENE
****
Il/La sottoscritto/a dichiara di essere consapevole delle sanzioni previste in caso di dichiarazioni false o mendaci (art.76 del Testo unico, D.P.R. 28.12.2000, n. 445).

Test Report

(Electronic version)

No:20R001104MO

VERIFICATION WEBSITE: www.gttc.net.cn
VERIFICATION CODE: ECUA-8716-44

ISSUE DATE 签发日期:2020-05-29

APPLICANT: HUNAN EEXI TECHNOLOGY&SERVICE CO.,LTD.
委托单位:
ADDRESS: NO.6, NORTH OF PINGTOU ROAD, LIUYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE, HUNAN,
地 址: CHINA

INFORMATION CONFIRMED BY APPLICANT 客户认定信息:

DISPOSABLE MEDICAL FACE MASK 一次性使用医用口罩 100个

MODEL 型号: YX005

SIZE 尺寸: 14.5cm×9cm

STANDARD ADOPTED 检验依据:

EN 14683:2019+AC:2019 〈Medical face masks-Requirements and test methods〉《医用口罩 要求与测试方法》

DATE RECEIVED/DATE TEST STARTED: 2020-05-09

样品受理/测试开始日期: 2020-05-09

CONCLUSION 结论:

Bacterial filtration efficiency (BFE) 细菌过滤效率（BFE）	M
Microbial cleanliness 洁净度-微生物	M
Differential pressure 压力差	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

REMARK:
MODIFIED CONTENT: MODIFIED CLIENT CONFIRMED INFORMATION.
更改内容：更改客户认定信息。
This report replaces test report 20R001104 which has become invalid automatically.
本报告代替20R001104报告，同时20R001104报告作废。
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
复印件、副本未重新加盖报告书确认章无效。
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.
本报告检验检测地址为广州市番禺区珠江路1号。

APPROVED BY(签发):

胡万丽 工程师

WanLi Hu ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Add: No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.
Tel: +86-20-61994598 61994599

Test Report

(Electronic version)

No: 20R001104MO

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Test Report

(Electronic version)

No: 20R001104MO

Bacterial filtration efficiency（BFE）
细菌过滤效率（BFE）
Test method: EN 14683: 2019+AC: 2019 Annex B
测试方法： EN 14683:2019+AC:2019 附录B

Test principle:
测试原理：
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.
把口罩材料的试样夹在六联冲击采样器和气溶胶室之间。将金黄色葡萄球菌的气雾引入到气溶胶室，并在真空状态下通过口罩和采样器。口罩的细菌过滤效率（BFE）等于通过医用口罩材料的菌落形成单位数与气溶胶室中的菌落形成单位数的比值，用百分数表示。

Test equipment:
测试设备：
Incubator
恒温培养箱
Electronic balance
电子天平
Autoclave
压力蒸汽灭菌锅
Experimental system for bacterial filtration efficiency (BFE) of mask
口罩细菌过滤效率（BFE）实验系统

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Total bacteria: 0 CFU/plate
细菌总数：0 CFU/皿
Total fungi: 0 CFU/plate
真菌总数：0 CFU/皿
Blank experiment: Aseptic growth
空白实验：无菌生长
Test environment temperature: 24.5℃, Relative humidity: 56.0%
测试环境温度：24.5℃，相对湿度：56.0%
Culture medium: TSA agar medium
培养基名称：TSA琼脂培养基
Culture temperature: 37℃, Culture time: 48h
样品培养温度：37℃，样品培养时间：48h
Test bacteria : staphylococcus aureus ATCC 6538
测试菌种：金黄色葡萄球菌ATCC 6538

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Test Report

(Electronic version)

No: 20R001104MO

Concentration of bacterium: 5.0×10^5 CFU /ml
菌液浓度：5.0×10^5 CFU /ml
Positive control average (C): 1.9×10^3 CFU
阳性质控平均值（C）： 1.9×10^3 CFU
Negative monitor count: ＜1 CFU
阴性质控值：＜1 CFU
Test area: 49 cm^2
测试面积：49 cm^2
Flow rate: 28.3 l/min
气体流速：28.3 l/min
Dimensions of the test specimens: 15cm×15cm
试样尺寸：15cm×15cm
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
预处理方式：温度（21±5）℃、相对湿度（85±5）%环境中预处理4h
Mean particle size: 3.0 μm
平均颗粒直径：3.0 μm
The medical face mask in contact with the bacterial challenge: inside
口罩与细菌气溶胶接触面：里层

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Test Report

(Electronic version)

No: 20R001104MO

Results 测试结果:

Sample 样品	T 计数之和	BFE 细菌过滤效率 (%)	Requirement 技术要求 (%)	Classification 级别	Conclusion 单项结论
1	30	98.42	≥95 EN 14683:2019+AC:2019	Type Ⅰ	Pass 符合
2	53	97.21			
3	43	97.74			
4	30	98.42			
5	35	98.16			

Remarks 备注:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

对于每个试样，按以下公式以百分比形式计算细菌过滤效率：

$B = (C - T) / C \times 100$

where 式中

B is bacterial filtration efficiency (BFE), %;

B---细菌过滤效率，%;

C is positive control average;

C---阳性质控平均值;

T is the total plate count for the test specimen.

T---试验样品计数之和。

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Test Report

(Electronic version)

No: 20R001104MO

Microbial cleanliness
洁净度-微生物
Test method: EN ISO 11737-1:2018, Membrane filtration
测试方法: EN ISO 11737-1:2018 膜过滤法

Test principle:
测试原理:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 μm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.
从原始包装中取出所需样品，在无菌条件下称取一定量的样品装放到无菌瓶中，其中含有300ml的萃取液（1g/l的蛋白胨，5g/lNaCl和2g/l吐温20）。在250rpm下振荡时间5min，量取100ml萃取液，用0.45μm的薄膜过滤后，将滤膜放置到TSA平板上，用于测定细菌菌落总数，取100ml萃取液，用0.45μm的薄膜过滤后，将滤膜放置到SDA平板上，用于测定真菌菌落总数。这些TSA和SDA平板分别在30℃下培养3天和20～25℃培养7天。总的微生物含量用TSA和SDA的计数和来表示。

Test equipment:
测试设备:
Constant temperature incubator
恒温培养箱
Electronic balance
电子天平
Pressure steam sterilizer
压力蒸汽灭菌锅
Biosafety cabinet
生物安全柜

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件:
Test environment temperature: 24.5℃, relative humidity: 56.0%
测试环境温度：24.5℃相对湿度：56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: sterile growth
测试环境监控：细菌总数：0 CFU/皿，真菌总数：0 CFU/皿，空白实验：无菌生长

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Test Report

(Electronic version)

No: 20R001104MO

Results 测试结果:

Sample 样品	Bacteria 细菌 (CFU/g)	Fungi 真菌 (CFU/g)	Microbial cleanliness 洁净度-微生物 (CFU/g)	Requirement 技术要求 (CFU/g)	Classification 级别	Conclusion 单项结论
1	7	3	10	≤30 EN 14683:2019+AC:2019	Type Ⅰ	Pass 符合
2	9	2	11			
3	6	3	9			
4	8	8	16			
5	10	2	12			

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Test Report

(Electronic version)

No: 20R001104MO

Differential pressure
压力差
Test method: EN 14683:2019+AC:2019 Annex C
测试方法：EN 14683:2019+AC:2019 附录C

Test principle:
测试原理：
This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.
通过口罩压力差测试仪，抽取空气以恒定的流速通过已经测定表面积的医用口罩材料，从而测定空气交换的压力差。

Test equipment:
测试设备：
GTTC-YLC-1 Apparatus for differential pressure
GTTC-YLC-1口罩压力差测试仪

The environmental conditions of the laboratory and test condition:
实验室环境条件和测试条件：
Air flow: 8 l/min
气体流量：8 l/min
Test area: 4.9cm^2
试验面积：4.9cm^2
Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
预处理方式：温度（21±5）℃、相对湿度（85±5）%环境中预处理大于4h
General location of the areas of the mask the differential measurements: specimen center
口罩压力差测试大概位置：试样中心

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Test Report

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No: 20R001104MO

Results 测试结果:

Sample 样品	Differential pressure 压力差 (Pa/cm²)	Requirement 技术要求 (Pa/cm²)	Classification 级别	Conclusion 单项结论
1	28.0	＜40 EN 14683:2019+AC:2019	Type Ⅰ	Pass 符合
2	25.3			
3	25.1			
4	22.9			
5	23.3			

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———本报告结束(End of Report)———

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