



BETTER AG

Spitzenqualität zum Herstellerpreis



Odem

Medizinische Einwegmasken

**Produkt: Medizinische Einwegmasken
EN 14683:2019**

Spezifikation: 17,5cm x 9,5cm

Anzahl der Schichten: 3 Lagen

Haltbarkeitsdauer: 3 Jahre

Verpackungsbox:

Menge: 50 Stück/Karton

Größe: 18 x 10 x 7

Verpackungskarton:

Quantität: 40 Stück/Karton

Größe: 52x38x30

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DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2016
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 20417: 2021
EN 14683:2019+AC:2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-XL-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Hubei Xianlu Medical & Health Products Co.,Ltd.
Address: 2-218 Building 2 No.35 Development Avenue,
Jinping Industrial Park Xiulin office, Shishou City, Hubei,
China 434400
SRN: CN-MF-000011495

Product Information

Name: DISPOSABLE FACE MASK (NON-STERILE)
Model: 17.5*9.5cm, 14.5*9.0cm
EMDN: T020604
Basic UDI-DI:
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2021.12.13

Position: GM

Place: Hubei/China





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检测报告

(Test Report)

No. BOYQMQR869707L1

样品名称
(Sample Description)

口罩
Face mask

委托单位
(Applicant)

湖北仙鹿医疗卫生用品有限公司
HUBEI Xianlu Medical&Health Products
Co.,Ltd.

PONY 谱尼测试
Pony Testing International Group
www.ponytest.com



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Statement

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检测结果 (Test Results)

No. BOYQMQJR869707L1

第 1 页, 共 2 页 (page 1 of 2)

样品名称 (Sample Description)	口罩 Face mask	样品规格 (Sample Specification)	规格 Specification: 17.5×9.5cm 型号 Model: 平面型 Plane
委托单位 (Applicant)	湖北仙鹿医疗卫生用品 有限公司 HUBEI Xianlu Medical&Health Products Co.,Ltd.	商标 (Trade Mark)	—
到样日期 (Received Date)	2020-04-09	生产日期或批号 (Manufacturing Date or Lot No.)	生产日期 Manufacturing Date: 2020.04.01 生产批号 Manufacturing Lot No.: 20200401
检测日期 (Test Date)	2020-04-09~2020-04-22	样品等级 (Sample Grade)	—
样品数量 (Sample Quantity)	80pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	包装完好 Packing Intact	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	电热恒温培养箱 Electric Heating Constant Temperature Incubator、 细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc.		
备注 (Note)	限值标准 Limit on: EN 14683: 2019 生产单位 Production: 湖北仙鹿医疗卫生用品有限公司 HUBEI Xianlu Medical&Health Products Co.,Ltd. 受检单位 Inspection: 湖北仙鹿医疗卫生用品有限公司 HUBEI Xianlu Medical&Health Products Co.,Ltd. 以上样品信息由委托单位提供 The information of above sample was provided by the applicant.		
	编制人 (Edited by)	王秋	
	审核人 (Checked by)	郭惠	
	批准人 (Approved by)	戴明	
	签发日期 (Issued Date)	2020-04-22	

检测结果 (Test Results)

No. BOYQMQJR869707L1

第 2 页, 共 2 页 (page 2 of 2)

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	限值 (Limit)			检测结果 (Test Results)		样品名称和编号 (Sample Description and Number)
		I 型 Type I	II 型 Type II	IIR 型 Type IIR			
R869707L1 口罩 Face mask	细菌过滤效率 (BFE), % Bacterial filtration efficiency(BFE)	≥95	≥98	≥98	No.1	99.2	EN 14683: 2019
					No.2	99.4	
					No.3	99.4	
					No.4	99.3	
					No.5	99.3	
	压力差, Pa/cm ² Differential pressure	<40	<40	<60	35.5		EN 14683: 2019
	抗溅压力, kPa Splash resistance pressure	/	/	≥16.0	>16.0		EN 14683: 2019
	微生物清洁度, cfu/g Microbial cleanliness	≤30	≤30	≤30	22		EN 14683: 2019

样品编号和照片 (Sample Number and Photo):



仅对报告照片中的样品负责
Pony authenticate the photo on original report only
——以下空白——
(End of Report)

