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 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-DY-01-02.

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: Guangzhou Dayun Medical Technology Co., Ltd.

Address: No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guangdong, China

Product Information

Name: Disposable Medical Mask（Non-Sterile）

Model： DY-01 (17.5cm × 9.5cm), DY-02 (14.0cm × 9.0cm), DY-03 (12.0cm × 7.0cm), TGL-03 (17.5 × 9.5cm)

GMDN: 35177

Basic UDI- DI: 697308854mask0122

Classification: Class I

Declaration

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

Name: Feng Jian

Signature:

Date:5th of Feb 2021

Position: General Manager

Place: Guangzhou / China

PONY 谱尼测试
Pony Testing International Group

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检 测 报 告

(Test Report)

No. GOLL5F8P189175L1

样品名称 (Sample Description)	一次性使用医用口罩（非灭菌） Disposable medical mask（Non-sterile）
委托单位 (Applicant)	广州达运医疗科技有限公司 Guangzhou Dayun Medical Technology Co.,Ltd.

PONY 谱尼测试
Pony Testing International Group

声 明
Statement

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检 测 结 果
(Test Results)

No. GOLL5F8P189175L1

样品名称 (Sample Description)	一次性使用医用口罩（非灭菌） Disposable medical mask （Non-sterile）	样品规格 (Sample Specification)	14.5cm *9.5cm
委托单位 (Applicant)	广州达运医疗科技有限公司 Guangzhou Dayun Medical Technology Co.,Ltd.	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-10-09	生产日期或批号 (Manufacturing Date or Lot No.)	20201008 20201008
检测日期 (Test Date)	2020-10-09~2020-10-20	样品等级 (Sample Grade)	——
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩颗粒物过滤效率及气流阻力测试仪 等 Respirator particle filtration efficiency and airflow resistance tester etc.		
备注 (Note)	1.型号：DY-02 Model：DY-02 2.生产单位/受检单位：广州达运医疗科技有限公司 Manufacturer/Tested company：Guangzhou Dayun Medical Technology Co.,Ltd. 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant. 5.限值标准：BS EN 14683:2019（IIR 型） Limit Standard：BS EN 14683:2019(Type IIR)		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)	张娜	
	审核人 (Checked by)	张慧玲	
	批准人 (Approved by)	孙水增	
	签发日期 (Issued Date)	2020 年 10 月 20 日	

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检 测 结 果
(Test Results)

No. GOLL5F8P189175L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)			单项结论 (Evaluation)	检测方法 (Test Method)
1	细菌过滤效率（BFE） Bacterial filtration efficiency(BFE)	%	≥98	99.91			符合 Pass	BS EN 14683:2019 附录 B Appendix B
				99.76				
				99.91				
				99.95				
				99.72				
2	压力差 Differential pressure	Pa/cm^2	<60	A	B	C	符合 Pass	BS EN 14683:2019 附录 C Appendix C
				1-1	22.2			
				1-2	22.3			
				1-3	23.4	21.8		
				1-4	20.2			
				1-5	21.1			
				2-1	27.1			
				2-2	20.9			
				2-3	21.9	25.6		
				2-4	25.7			
				2-5	32.2			
				3-1	25.0			
				3-2	14.8			
				3-3	17.5	22.0		
				3-4	23.2			
				3-5	29.4			
				4-1	23.7			
				4-2	24.5			
				4-3	21.3	21.8		
				4-4	16.8			
				4-5	22.9			
				5-1	22.4			
				5-2	22.2			
				5-3	22.1	21.3		
				5-4	21.7			
				5-5	17.9			

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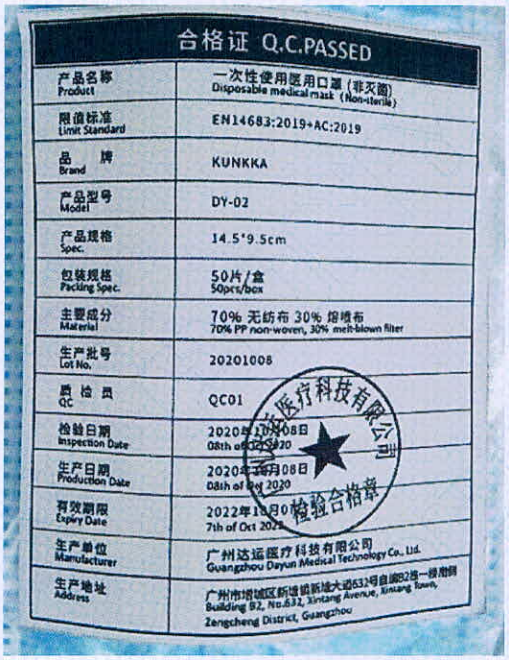
检 测 结 果
(Test Results)

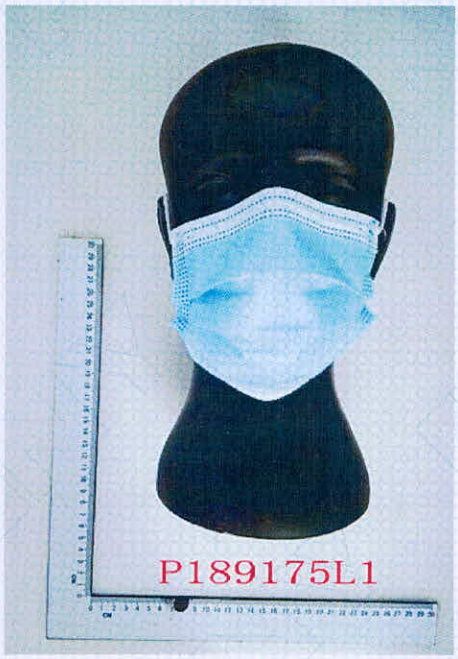
No. GOLL5F8P189175L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	限值 (Limit)	检测结果 (Test Result)	单项结论 (Evaluation)	检测方法 (Test Method)
3	抗溅压力 Splash resistance pressure	kPa	≥16.0	32 个试样均＞16.0 Splash resistance pressure of 32 samples were all greater than 16.0	符合 Pass	ISO 22609:2004
4	微生物洁净度 Microbial cleanliness	cfu/g	≤30	20	符合 Pass	BS EN 14683:2019 附录 D Appendix D
				21		
				13		
				16		
				20		

备注 Note：A-试样编号-测试区域编号 Test Specimen number-Test area number；B-每个测试区域的压力差 Differential pressure for each test area；C-每个试样的平均压差 The averaged differential pressure for each test specimen。

照片 Photo：





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