



**Dongguan
Mayo Medical
Technology Co., Ltd**


ENVIRONMENT



ENVIRONMENT



BUSINESS LICENSE

		 *440411748*
统一社会信用代码 91441900MA54DUFWXR		<h2 style="color: yellow;">营业执照</h2>
(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 东莞市梅奥医疗器械科技有限公司	注册资本 人民币壹佰万元	
类型 有限责任公司(自然人投资或控股)	成立日期 2020年03月17日	
法定代表人 王志	营业期限 长期	
经营范围 研发、产销:第一类、第二类、第三类医疗器械、劳保用品、劳动防护用品、日用百货(非医用);货物或技术进出口(国家禁止或涉及行政审批的货物和技术进出口除外)。(依法须经批准的项目,经相关部门批准后方可开展经营活动) 二	住所 广东省东莞市虎门镇路东新二路1号2栋301房	
登记机关		 2020年 3月 30日
国家企业信用信息公示系统网址: http://www.gsxt.gov.cn		国家市场监督管理总局监制
市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告		

Registration Form for Foreign Trade Business

对外贸易经营者备案登记表

备案登记编号: 04829898

统一社会信用代码: 91441900MA54DUFWXR
进出口企业代码: _____

经营者中文名称	东莞市梅奥医疗器械科技有限公司		
经营者英文名称	Dongguan Mayo Medical Technology Co.,Ltd;		
组织机构代码	_____	经营者类型 (由各登记机关填写)	有限责任公司
住 所	广东省东莞市虎门镇路东新二路4号2栋		
经营场所 (中文)	广东省东莞市虎门镇路东新二路4号2栋		
经营场所 (英文)	building 2, No. 4, Ludong Xin ERoad, Humen Town, Dongguan City, Guangdong Province		
联系电话	18126818383	联系传真	_____
邮政编码	523899	电子邮箱	66314110@qq.com
工商登记注册日期	2020-3-17	工商登记注册号	_____

依法办理工商登记的企业还请填写以下内容

企业法定代表人姓名	王志	有效证件号	350321199208095213
注册资金	壹佰万元		(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 / 个体工商户负责人姓名	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户负责人签字、盖章。



2020 年 04 月 15 日

Class II Medical Device License

№ 0004621



第二类医疗器械经营备案凭证

备案编号：粤东食药监械经营备20201331号

企业名称	东莞市梅奥医疗器械科技有限公司
法定代表人	王志
企业负责人	王志
经营方式	批零兼营
住 所	广东省东莞市虎门镇路东新二路4号2栋
经营场所	广东省东莞市虎门镇路东新二路4号2栋
库房地址	广东省东莞市虎门镇路东新二路4号2栋
经营范围	2002年分类目录:6801, 6815, 6820, 6823, 6826, 6827, 6840 (体外诊断试剂除外), 6846, 6854, 6864, 6866 2017年分类目录:

备案部门 (公章)

备案日期: 2020年 6 月 29 日

Class II Medical Device License

海关进出口货物收发货人备案回执

企业名称	东莞市梅奥医疗器械科技有限公司
统一社会信用代码	91441900MA54DUFWXR
海关备案日期	2020-04-16
海关编码	4419960ZVG
检验检疫备案号	5654200590
有效期	长期



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。

White List CE NB Certified FFP2

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取得国外标准认证或注册的医疗物资和非医用品生产型企业检索

企业名称 (中文)	企业名称 (英文)	产品类型	统一社会信用代码	国外标准认证情况
东莞市美蓝医疗科技有限公司	Dongguan Mayo Medical Technology Co., Ltd.	非医用口罩	91441900MA54DUFWX3	欧盟CE

企业ID	企业名称 (中文)	企业名称 (英文)	产品类型	统一社会信用代码	国外标准认证情况
3676	广东蓝盾(东莞)医疗器械有限公司 Guangdong Lanshield (Dongguan) Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3770	深圳市美蓝医疗科技有限公司 Shenzhen Mayo Medical Technology Co., Ltd.		医用口罩	91440303MA54DUFWX3	欧盟CE
3780	广东蓝盾(东莞)医疗器械有限公司 Guangdong Lanshield (Dongguan) Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3783	广东蓝盾(东莞)医疗器械有限公司 Guangdong Lanshield (Dongguan) Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3785	东莞市美蓝医疗科技有限公司 Dongguan Mayo Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3787	东莞市美蓝医疗科技有限公司 Dongguan Mayo Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3793	广东蓝盾(东莞)医疗器械有限公司 Guangdong Lanshield (Dongguan) Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE
3820	广东蓝盾(东莞)医疗器械有限公司 Guangdong Lanshield (Dongguan) Medical Technology Co., Ltd.		医用口罩	91441900MA54DUFWX3	欧盟CE

NB 0370 CE PPE/ MODULE B

LGA Technological Center, S.A. (APPLUS)
Campus UAB - Ronda de la Font del Carme s/n
08193 Bellaterra (Barcelona)
T +34 93 567 20 00
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CERTIFICADO DE EXAMEN UE DE TIPO EU-TYPE EXAMINATION CERTIFICATE



No. **0370-4106-PPE/B**

ORGANISMO NOTIFICADO N° <i>NOTIFIED BODY NUMBER</i>	0370 - LGA1 TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE <i>APPLICANT</i>	Dongguan Mayo Medical Technology Co., Ltd. No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China
FABRICANTE <i>MANUFACTURER</i>	Dongguan Mayo Medical Technology Co., Ltd. No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD <i>CONFORMITY ASSESSMENT PROCEDURE</i>	Módulo // <i>Module</i> : B EXAMEN UE DE TIPO EU TYPE EXAMINATION
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MY-001 Particle Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
NORMAS ARMONIZADAS HARMONISED STANDARDS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. <i>EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking</i>
FECHA DE EMISIÓN ISSUE DATE	27/07/2020
VALIDEZ HASTA VALIDITY UNTIL	27/07/2025
El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).	
<i>This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D (carried out by a Notified Body according to the established frequency).</i>	



LGA1 Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

Puede comprobarse la validez de este certificado en nuestra página web / You can check the validity of this certificate into our website at <https://www.applus.com/thiscertificate/thiscertificate/EC273949>

NB 0370 CE PPE/ MODULE B

IGAT Technological Center, S.A. (APPLUS)
 Campus UAB – Ronda de la Font del Gall, s/n
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Technical Annex Ed. 1
 27/07/2020

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4106-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA <i>BRAND</i>	Dr. ITC
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MY-001 Particle Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
INFORME DE ENSAYO <i>TEST REPORT</i>	PTC20061606501C-EN01V02 issued by Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)

NB 0370 CE PPE/ MODULE C2

LGAI Technological Center, S.A. (APPLUS)
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CERTIFICADO DE CONFORMIDAD CON EL TIPO CONFORMITY TO TYPE CERTIFICATE



Designated Certificate Nº 0370



No. **0370-4160-PPE/C2**

ORGANISMO NOTIFICADO Nº NOTIFIED BODY NUMBER	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE APPLICANT	Dongguan Mayo Medical Technology Co., Ltd. No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China
FABRICANTE MANUFACTURER	Dongguan Mayo Medical Technology Co., Ltd. No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO CONFORMITY ASSESSMENT PROCEDURE TO TYPE	Módulo // Module C2 SASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) IDENTIFICATION OF THE PPE (TYPE NUMBER)	Ref.: MY-001 Particle Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
FECHA DE EMISIÓN / ISSUE DATE	06/08/2020
VALIDEZ HASTA / VALIDITY UNTIL:	06/08/2021
El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo. This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.	



Xavier Ruiz Peña
 Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
 This document is not valid without its technical annex, whose number coincides with the number of certificate.

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Technical Annex Ed. 1
 06/08/2020

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4160-PPE/C2

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

Nº CERTIFICADO DE EXAMEN UE DE TIPO <i>NR. EU TYPE EXAMINATION CERTIFICATE</i>	0370-4106-PPE/B
EMITIDO POR <i>ISSUED BY</i>	LGA1 TECHNOLOGICAL CENTER S.A. (APPLUS) (Organismo notificado nº 0370 / Notified Body nr. 0370).
FECHA EMISIÓN <i>ISSUE DATE</i>	27/07/2020
VALIDEZ HASTA <i>VALIDITY UNTIL</i>	27/07/2025
MARCA <i>BRAND</i>	Dr. ITC
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MY-001 Particle Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
INFORME DE ENSAYO DE CONFORMIDAD CON EL TIPO <i>CONFORMITY TO TYPE TEST REPORT</i>	PTC20072001501C-EN01 issued by Precise Testing & Certification (Guangdong) Co., Ltd.(PTC).

NB0370 FFP2 TEST REPORT



中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M3 PPE) of Applus+, the test item(s) of the sample is according to the standard EN149:2001+A1:2009.

Product: Particle filtering half mask

Report No.: PTC20072001501C-EN01

APPLUS +With ID number: 20/32301328

Client: Dongguan Mayo Medical Technology Co.,Ltd

Client Address: No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China

Manufacturer: Dongguan Mayo Medical Technology Co.,Ltd

Manufacturer Address: No. 4 Dongxin 2 Road, Humen Town, Dongguan, Guangdong Province, China

Contact: /

Model(s): My-001

Classification: FFP2 NR

Date of Tests: 2020.07.23~2020.07.31

Signed for and on Behalf of PTC

Prepare by:

Checked by:



Arme

Jme

Lin Mo

This report is issued according to the general clauses in www.ptc-testing.com by PTC. Responsibility, guarantee and law restriction are defined in the general service clauses. The report is only responsible for the submitted sample(s) except an otherwise stated. The report could not be copied without permission.

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38805222 Fax: 86-769-38826111 <http://www.ptc-testing.com>

NB0370 FFP2 TEST REPORT



Test Report

Report No.: PTC20072001501C-EN01

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Summary of assessment

Clause	Assessment
7.3 Visual inspection	PASS
7.5 Material	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.16 Breathing resistance	PASS

Remark:

PASS: comply with requirement of standard

N/A: not application

Not tested: the clause were not required

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Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
 Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
 Tel: 86-769-38808222 Fax: 86-769-38626111 <http://www.ptc-testing.com>

NB0370 FFP2 TEST REPORT



Test Report

Report No.: PTC20072001501C-EN01

Issue Date: Aug.03, 2020

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Table 7.9.2: Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment	
Sodium chloride test	As received	11	0.04	FFP2 Pass	
		12	1.15		
		13	0.04		
	Simulated wearing treatment	Mechanical strength + Temperature conditioned	14		0.02
			15		0.02
			16		0.12
			17		0.35
			18		0.17
			19		0.05
Paraffin oil test	As received	20	0.42		
		21	0.70		
		22	0.57		
	Simulated wearing treatment	Mechanical strength + Temperature conditioned	23		1.37
			24		0.97
			25		0.25
			26		0.39
			27		0.67
			28		0.37

Table 7.12: Carbon dioxide content of the inhalation air

Test specification: EN 149:2001+A1:2009 Clause 8.7

Condition	Sample No.	Result (%)	Assessment
As received	29	0.0096	Pass
	30	0.0121	
	31	0.0142	
		Mean value: 0.012	

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Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
 Building 1, No. 6, Tongmen Road, Dongcheng Street, Dongguan, Guangdong, China.
 Tel: 86-769-33803222 Fax: 86-769-33802111 http://www.ptc-testing.com

NB0370 FFP2 TEST REPORT



Test Report

Report No.: PTC20072001501C-EN01

Issue Date: Aug.03, 2020

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Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

As received	Flow Rate		32					33					34				
	Inhalation	30 l/min	0.50					0.48					0.46				
		95 l/min	1.39					1.37					1.39				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.1	2.1	2.1	2.1	2.1	2.0	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2
Flow Rate		35					36					37					
Simulated wearing treatment	Inhalation	30 l/min	0.40					0.40					0.43				
		95 l/min	1.36					1.37					1.38				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.0	2.0	1.9	1.9	1.9	1.9	2.0	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0
	Flow Rate		38					39					40				
Temperature conditioned	Inhalation	30 l/min	0.38					0.38					0.39				
		95 l/min	1.38					1.39					1.36				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.0	2.0	2.0	2.0	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
	Flow Rate		38					39					40				
Assessment		FFP2, Pass															

A: Facing directly ahead B: Facing vertically upwards C: facing vertically downwards

D: Lying on the left side E: Lying on the right side

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 Building 1, No. 6, Tongren Road, Dongcheng Street, Dongguan, Guangdong, China.
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NB0370 FFP2 TEST REPORT



Test Report

Report No.: PTC20072001501C-EN01

Issue Date: Aug.03, 2020

Page 7 of 11

Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

	Flow Rate		32					33					34				
	As received	Inhalation	30 l/min	0.50					0.48					0.46			
95 l/min			1.39					1.37					1.39				
Exhalation		160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
			2.1	2.1	2.1	2.1	2.1	2.0	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2
Simulated wearing treatment	Flow Rate		35					36					37				
	Inhalation	30 l/min	0.40					0.40					0.43				
		95 l/min	1.36					1.37					1.38				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
2.0			2.0	1.9	1.9	1.9	1.9	2.0	1.9	1.9	1.9	2.0	2.0	2.0	2.0	2.0	
Temperature conditioned	Flow Rate		38					39					40				
	Inhalation	30 l/min	0.38					0.38					0.39				
		95 l/min	1.38					1.39					1.36				
	Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
2.0			2.0	2.0	2.0	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
Assessment	FFP2, Pass																

A: Facing directly ahead B: Facing vertically upwards C: facing vertically downwards
 D: Lying on the left side E: Lying on the right side

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MASK TYPE

1000个口罩尺寸如下:

即一盒两包,一包10个,一箱50盒

单个纸盒尺寸:23×15×4.5cm

成品纸箱尺寸:77×48×24.5cm



MATERIALS

40,54%
**NON-WOVEN
FABRIC**

32,43%
**ES HOT AIR
COTTON**

27,03%
**MELT-BLOWN
FABRIC**

