

Test Report **SL52025256570301TX** **Date: May 18, 2020** **Page 1 of 3**
MAJESTIC SAFETY PRODUCTS & SERVICES B.V.
P.O. BOX 80, 3200 AB SPIJKENISSE, THE NETHERLANDS.

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Disposable surgical face mask: Type IIR (Claimed Type IIR)
Style No. : M-Safe 5053
Composition : (A) PP
Sample Color : (A) Blue
End Use : (A) health care
Buyer : EU
Order No. : M123899
Country of Destination : The Netherlands
Country of Origin : China
Proposed Care Instruction : -
Test Performed : Selected test(s) as requested by applicant
Sample Receiving Date : May 06, 2020
Testing Period : May 06, 2020 - May 18, 2020
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Comment:

Medical Face Masks-Requirements and Test Methods(EN 14683:2019)	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019 Type IIR requirement

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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Test Result

Medical Face Masks-Requirements and Test Methods

(EN 14683:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)**

	1#	2#	3#	4#	5#
(BFE), %	>99.9	>99.9	>99.9	>99.9	>99.9

Remark: Performance Requirement: Type I>95%, Type II>98%, Type IIR >98%

** : This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation)

Clause 5.2.3 Breathability (Differential Pressure)

(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	37	38	37	38	38

Remark: Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Fail	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			30				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results



Clause 5.2.5 Microbial Cleanliness
(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	14	22	21	18	13

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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Postbus 80
3200 AB Spijkenisse
Nederland

verklaart op eigen verantwoording dat het product met CE-markering, zoals hieronder beschreven:

M-Safe 5057 disposable chirurgisch mondmasker Type IIR

Kleur: blauw • Artikelnummer: 4.05.057.00

- is geclassificeerd volgens regel 1 van bijlage IX van de Medische Richtlijn 93/42/EEG betreffende medische hulpmiddelen als een (niet-steriel) product van klasse I;
- en dat het in overeenstemming is met bijlage VII en alle andere toepasselijke bepalingen van de Richtlijn 93/42/EEG betreffende medische hulpmiddelen inzake de onderlinge aanpassing van de wetgevingen van de lidstaten van de Europese Unie inzake medische hulpmiddelen;
- en dat het in overeenstemming is met de Europese norm EN 14683:2019 (type IIR).

Alle ondersteunende documentatie wordt bewaard door de fabrikant.

Opgemaakt te Spijkenisse, 27-04-2020



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- en dat het in overeenstemming is met de Europese norm EN 14683:2019 (type IIR).

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M-Safe 5055 disposable chirurgisch mondmasker Type IIR

Kleur: blauw • Artikelnummer: 4.05.055.00

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- en dat het in overeenstemming is met bijlage VII en alle andere toepasselijke bepalingen van de Richtlijn 93/42/EEG betreffende medische hulpmiddelen inzake de onderlinge aanpassing van de wetgevingen van de lidstaten van de Europese Unie inzake medische hulpmiddelen;
- en dat het in overeenstemming is met de Europese norm EN 14683:2019 (type IIR).

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