

MAFGuardTM

Ensuring Care, Comfort & Compliance

Disposable 3 Ply Mask





MAFGuard

By: MAF Clothing Pvt. Ltd.



THE RIGHT FACIAL PROTECTION: Disposable Face Mask

The most important element in selecting a face mask is the confidence that comes from knowing that both you and your patients are adequately protected. Not all face masks are created equal; some masks have a higher level of protection than others. At MAF Guard, we display the American Society for Testing and Materials (ASTM) International Standards for face masks on our packaging, so that you can face the unknown, knowing you're protected.

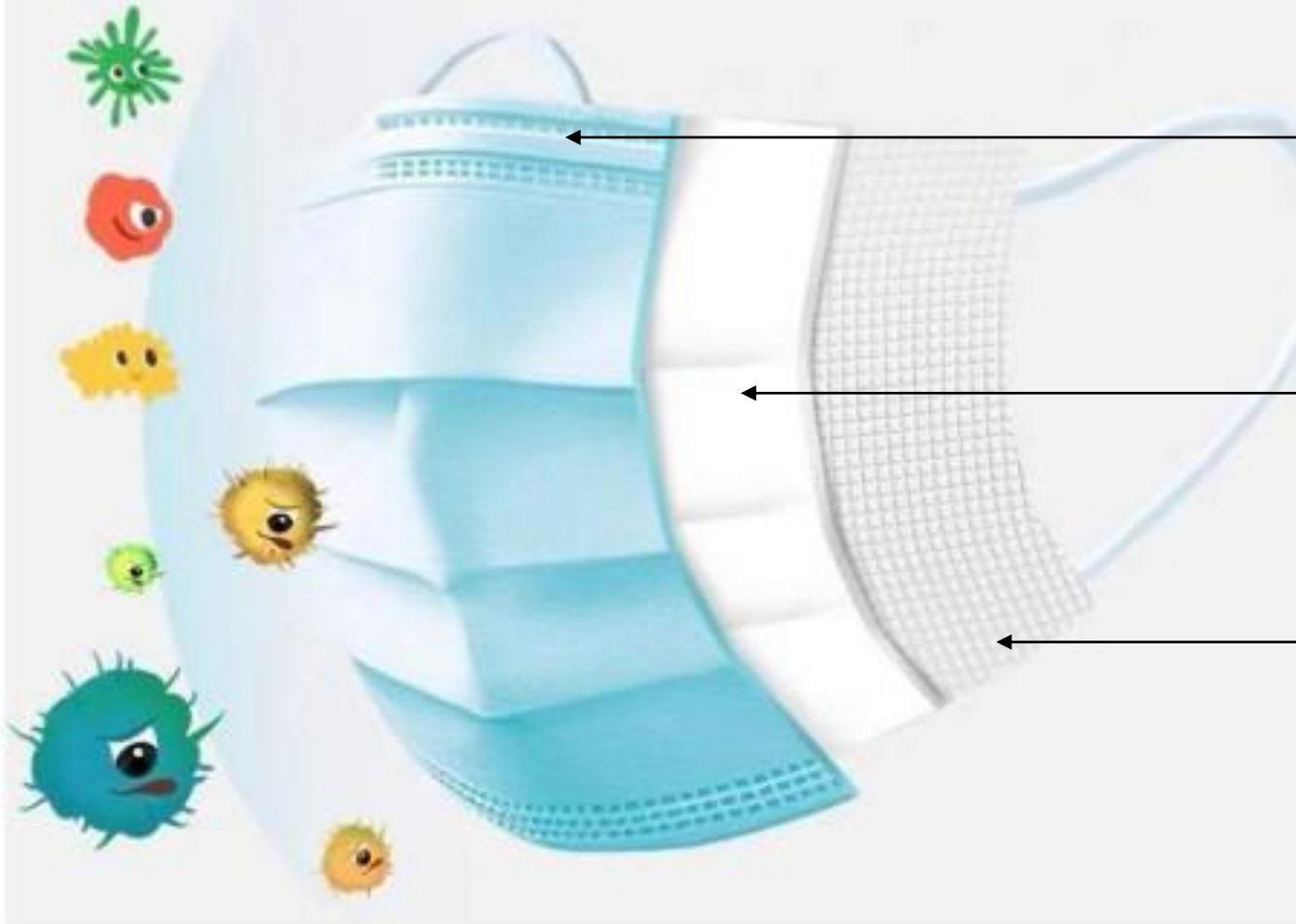
MEDICAL FACE MASK TESTS AND REQUIREMENTS

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH ₂ O/cm ²	<6.0 mmH ₂ O/cm ²		<40 Pa/cm ²		<60 Pa/cm ²
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		<ul style="list-style-type: none"> AQL 4% for BFE, PFE, Delta P 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) 14 masks for Flammability 			<ul style="list-style-type: none"> Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) 		

3 LAYERS OF PROTECTION

Protective Mask



Outer Layer:
Hydrophobic Non Woven

Middle Layer:
Melt Blown Filter

Inner Layer:
Hydrophilic, soft absorbent
Non Woven

Unique Multiple Filtration Layer

MAF Guard's fluid resistant facemasks were designed from end user feedback to offer best-available protection and comfort. Manufactured in the India using soft, breathable materials, our facemasks feature comfortable earloops for long-wear, and surpass protection standards.



Factory Set Up

Manufacturing facility is installed with state-of-the-art automated machine, fully airconditioned environment having clean room systems implemented. It is ISO 13485, GMP, FDA Compliant, ISO 9001, ISO 14001 and WRAP Gold certified facility, with monthly production capacity of 6 million masks.




Pack Size Includes


- Box of 50 pcs.....40 boxes in a carton (2000 pcs)
- Zip lock Pouch of 10 pcs.....200 pouches in a carton (2000 pcs)




Test Report ASTM F2100

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 **Test Report**

Report Code AR-20-M6-000789-01

Sample No 210-2020-06000068
Report Date 12.06.2020

Sample Photo



Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur,
Tamilnadu-641603, India

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 **Test Report**

Report Code AR-20-M6-000789-01

Sample No 210-2020-06000068
Report Date 12.06.2020

Applicant : MAF Clothing Pvt Ltd
Contact person : Mr.Kint, Mr.Srinivas, Ms.Sandhya
Address : Adakamranahalli Makali Post, Tumkar Road, 21ST KM,
Bangalore - 562123

Sample Not Drawn By Eurofins Product Testing India Pvt. Ltd.
Sample Description : Mask
Buyer Name : Self Reference
Buying House : -
PO No. : -
Fiber Content : -
Style No. : -
Colour Name : Blue
End Use : -
GSM : -
Country of Origin : India
Sample Receiving Date : 05 Jun 2020
Testing Period : 06 Jun 2020 to 12 Jun 2020
Delivery Condition : Sample received in good condition.
Applicant's Provided Care Instruction /label : -

For and on behalf of
Eurofins Product Testing India Pvt. Ltd




Arasu MA
Manager – Lab Operations

Results obtained refer only to samples, products or material received in Laboratory, as described in point related to sample description, and tested in conditions shown in present report. Eurofins Products Testing Pvt. Ltd. Ensures that this job has been performed according to our Quality System and complying contract and legal conditions. If you happen to have any comments, please do it by sending email to naarendran@eurofins.com and referring to this report number. Reproduction of this document is only valid if it is done completely and under the written permission Eurofins Products Testing Pvt. Ltd.


Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur,
Tamilnadu-641603, India

Test Report ASTM F2100

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Test Report

Report Code AR-20-M6-000789-01

 Sample No 210-2020-06000068
 Report Date 12.06.2020

Conclusion:

Test Property	Pass	Fail	Remarks
Breathability Test (Differential Pressure Pa)	X		Level 1/ Level 2 / Level 3
Bacterial Filtration efficiency(BFE)	X		Level 1/ Level 2 / Level 3
Splash Resistance/Fluid Penetration- Resistance To Blood	X		Level 1/ Level 2 / Level 3
Flammability	X		Class 1


Remark: Testing has been performed as per applicant request.

Note:
If there is question or concern regarding the above results, please contact the appropriate lab person below:


Arasu MA
ArasuMA@eurofins.com
 Or
 Narender Arya
 General Manager (India Business)
narenderarya@eurofins.com
The testing lab overall rating is provided to client as an aid in reviewing report data. The rating is based on lab results. Final product acceptance or rejection is per client only. Testing of vendor's merchandise by client is not a substitute for vendor's own testing and other quality assurance related obligations in connection with its sale of merchandise to client. Client testing shall not limit client's rights, or diminish or remove any of vendor's responsibilities.

Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur, Tamilnadu-641603, India

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Test Report

Report Code AR-20-M6-000789-01

 Sample No 210-2020-06000068
 Report Date 12.06.2020

Component List:

Sample No	Component	Material Description	Color	Remarks
001	Mask	-	Blue	-

Breathability Test (Differential Pressure Pa)*
 EN 14683 (Annex C) : 2019

SAMPLE	Average Result (mm H ₂ O/cm ²)	Requirement
001		
Differential Pressure	2.72	Level 1- <5mm H ₂ O/cm ² Level 2- <6mm H ₂ O/cm ² Level 3- <6mm H ₂ O/cm ²

Bacterial Filtration efficiency(BFE)*
 ASTM F 2101:2019

SAMPLE	Average Result (%)	Requirement
001		
Bacterial Filtration efficiency(BFE)	98.10	Level 1 ≥ 95% Level 2 ≥ 98% Level 3 ≥ 98%

Splash Resistance/Fluid Penetration- Resistance To Blood*
 ASTM F1862/ F1862M-17

SAMPLE001	Result	Requirement
Result @ 160 mmHg	Pass	Level 1 – 80 mmHg Level 2 – 120 mmHg Level 3 – 160 mmHg

Remark: Synthetic blood applied at particular pressure should not pass through other side of the fabric.
 Note: No. of samples tested: 32

Flammability
 16 CFR 1610

SAMPLE	Result	Requirement
001	✓ Plain Surface	
Final Classification (As Received)	Class 1	Class 1


*Remark: The test has been subcontracted to Eurofins approved laboratory


**** End of Report *****

Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur, Tamilnadu-641603, India

Test Report ASTM F2100


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 **Test Report**

Report Code AR-20-M6-000853-01



Sample No 210-2020-06000183
Report Date 17.06.2020


Sample Photo



Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur, Tamilnadu-641603, India

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 **Test Report**


Report Code AR-20-M6-000853-01


Sample No 210-2020-06000183
Report Date 17.06.2020

Applicant : MAF Clothing Pvt Ltd
Contact person : Mr.Kirit, Mr.Srinivas, Ms.Sandhya
Address : Adakamaranahalli Makali Post, Tumkar Road, 21ST KM, Bangalore - 562123

Sample Not Drawn By Eurofins Product Testing India Pvt. Ltd.

Sample Description : 3Ply Face Mask
Buyer Name : Self Reference
Buying House : -
PO No. : -
Fiber Content : -
Style No. : -
Colour Name : Blue
End Use : Mask
GSM : -
Country of Origin : India
Sample Receiving Date : 15 Jun 2020
Testing Period : 15 Jun 2020 to 17 Jun 2020
Delivery Condition : Sample received in good condition.
Applicant's Provided Care Instruction /label : -

For and on behalf of
Eurofins Product Testing India Pvt. Ltd


Arasu MA
Manager - Lab Operations

Results obtained refer only to samples, products or material received in Laboratory, as described in point related to sample description, and tested in conditions shown in present report. Eurofins Products Testing Pvt. Ltd. Ensures that this job has been performed according to our Quality System and complying contract and legal conditions. If you happen to have any comments, please do it by sending email to narendaraya@eurofins.com and referring to this report number. Reproduction of this document is only valid if it is done completely and under the written permission Eurofins Products Testing Pvt. Ltd.

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Test Report ASTM F2100



Test Report

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Report Code AR-20-M6-000853-01



Sample No 210-2020-06000183

Report Date 17.06.2020

Conclusion:

Test Property	Pass	Fail	Remarks
Particulate Filtration Efficiency at 0.3 Microns	X		Level 1 / Level 2 / Level 3

Remark: Testing has been performed as per applicant request.

Note:

If there is question or concern regarding the above results, please contact the appropriate lab person below:

Arasu MA

ArasuMA@eurofins.com

Or

Narender Arya

General Manager (India Business)

narenderarya@eurofins.com

The testing lab overall rating is provided to client as an aid in reviewing report data. The rating is based on lab results. Final product acceptance or rejection is per client only. Testing of vendor's merchandise by client is not a substitute for vendor's own testing and other quality assurance related obligations in connection with its sale of merchandise to client. Client testing shall not limit client's rights, or diminish or remove any of vendor's responsibilities.



Test Report

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Report Code AR-20-M6-000853-01



Sample No 210-2020-06000183

Report Date 17.06.2020

Component List:

Sample No	Component	Material Description	Color	Remarks
001	3Ply Face Mask	-	Blue	-

Particulate Filtration Efficiency at 0.3 Microns *

ASTM F2299 / F2299M-03(2010)


SAMPLE	Average Result (%)	Requirement
001		
Particulate Filtration Efficiency	98.02	Level 1 ≥ 95% Level 2 ≥ 98% Level 3 ≥ 98%


*Remark: The test has been subcontracted to Eurofins approved laboratory

**** End of Report ****


Test Report EN 14683 : 2019

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 **Test Report**


Report Code AR-20-M6-000890-01

Sample No 210-2020-06000067
Report Date 20.06.2020

Sample Photo



Entrofin Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur,
Tamilnadu-641603, India

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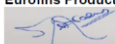
 **Test Report**

Report Code AR-20-M6-000890-01

Sample No 210-2020-06000067
Report Date 20.06.2020

Applicant : MAF Clothing Pvt Ltd
Contact person : Mr.Kirit, Ms.Sandhya, Mr.Srinivas
Address : Adakamaranahalli Makali Post, Tumkur Road, 21st KM,
Bangalore-562123

Sample Not Drawn By Eurofins Product Testing India Pvt. Ltd.
Sample Description : Face Mask
Buyer Name : Self Reference
Buying House : -
PO No. : -
Fiber Content : -
Style No. : -
Colour Name : Blue
End Use : -
GSM : -
Country of Origin : India
Sample Receiving Date : 05 Jun 2020
Testing Period : 06 Jun 2020 to 20 Jun 2020
Delivery Condition : Sample received in good condition.
Applicant's Provided Care Instruction /label : -


For and on behalf of
Eurofins Product Testing India Pvt. Ltd

Arasu MA
Manager – Lab Operations

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Tamilnadu-641603, India

Test Report EN 14683 : 2019

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Test Report

Report Code AR-20-M6-000890-01

 Sample No 210-2020-06000067
 Report Date 20.06.2020

Conclusion:

Test Property	Pass	Fail	Remarks
Breathability Test (Differential Pressure Pa)	X		Type I / Type II / Type IIR
Bacterial Filtration efficiency(BFE)	X		Type I / Type II / Type IIR
Splash Resistance/Fluid Penetration- Resistance To Blood	X		Type IIR
Microbial Cleanliness	X		Type I / Type II / Type IIR

Remark: Testing has been performed as per applicant request.


Note:
 If there is question or concern regarding the above results, please contact the appropriate lab person below:

Arasu MA
ArasuMA@eurofins.com
 Or
 Narender Arya
 General Manager (India Business)
narendearya@eurofins.com


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Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur, Tamilnadu-641603, India

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Test Report

Report Code AR-20-M6-000890-01

 Sample No 210-2020-06000067
 Report Date 20.06.2020

Component List:

Sample No	Component	Material Description	Color	Remarks
001	Face Mask	-	Blue	-

Breathability Test (Differential Pressure Pa)*
 EN 14683 (Annex C) : 2019

SAMPLE	Result (Pa/cm ²)	Requirement
001		
Differential Pressure , Pa/cm ²	25.78	Type I <40 Pa/cm ² Type II <40 Pa/cm ² Type IIR <60 Pa/cm ²

Bacterial Filtration efficiency(BFE)*
 EN 14683 (Annex B) : 2019

SAMPLE	Average Result (%)	Requirement
001		
Bacterial Filtration efficiency(BFE)	98.05	Type I ≥ 95% Type II ≥ 98% Type IIR ≥ 98%

Splash Resistance/Fluid Penetration- Resistance To Blood*
 ISO 22609 : 2019

SAMPLE001	Result	Requirement
Result @ 16.0 kPa	Pass	Type IIR ≥ 16.0 kPa

Remark: Synthetic blood applied at particular pressure should not pass through other side of the fabric.

Microbial Cleanliness*
 EN 14683 (Annex D): 2019

SAMPLE	Average Result (cfu/g)	Requirement
001		
Microbial Cleanliness	14	Type I ≤30 cfu/g Type II ≤30 cfu/g Type IIR ≤30 cfu/g

*Remark: The test has been subcontracted to Eurofins approved laboratory

**** End of Report ****

Eurofins Product Testing India Pvt. Ltd. No.16C, Ramraj Nagar, 80 Feet Road, Gandhi Nagar, Avinashi Road, Tirupur, Tamilnadu-641603, India



2020

CERTIFICATE OF REGISTRATION

This certifies that:

MAF Clothing Pvt. Ltd.
Sy. No 59/3, 59/4 Rajathadripura
Near K B Cross, Tiptur Taluk Tumkur District
Tumkur District , IN 572114

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	10074202
Device Classification Name:	FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE QKR
Product Code:	Registrar Corp
Official Correspondent and U.S. Agent:	144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
David Lennarz
Executive Director
Registrar Corp
Dated: May 20, 2020



Scan this code with your smart phone
to verify the certificate



PARAMOUNT QUALITY CERTIFICATIONS

CERTIFICATE OF COMPLIANCE

CE

This is to certify that the Products Medical Equipment's Products & spares of class I according to the Medical Devices Directive 93/42/EEC manufactured by:

NAME: MAF CLOTHING PRIVATE LIMITED

**ADDRESS: MAF CLOTHING PVT LTD UNIT-3, SY. NO59/3, 59/4, RAJATHADRI PURA,
NEAR K B CROSS, TIPTUR TALUK, TUMKUR DISTRICT - 572114,
KARNATAKA, INDIA**

**PRODUCTS: MANUFACTURING AND SUPPLY OF SURGICAL MASKS, DUST MASK,
GENERAL N95 RESPIRATOR, EN 149 FFP2 MASK, N95 FFP2 MASK, MEDICAL
GOWNS, ALL PATIENT GOWNS, ISOLATION GOWN, SURGICAL GOWN, NON-
SURGICAL GOWNS, PROCEDURAL GOWNS, OPERATING ROOM GOWNS,
SURGICAL DRAPES, PPE KITS, PPE COVER ALL, CAP, SHOE COVER, FACE
MASK, ALL BED SHEET, TROLLEY SHEET, OT SHEETS, DRAPES AND APRON**

COMPLIES WITH THE REQUIREMENTS APPLICABLE TO IT

The Certification Body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives Medical Devices Directive 93/42/EEC.

THIS CERTIFICATE IS ISSUED UNDER THE FOLLOWING CONDITIONS:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certification Calendar:

Client Id: 740	Certificate No: 997/CE/190520
Registered on: 19.05.2020	Issued on: 19.05.2020
Expires on: 18.05.2023	
1 st Surveillance on/before: 18.05.2021	
2 nd Surveillance on/before: 18.05.2022	



Signature

Authorized Signatory





CERTIFICATE OF COMPLIANCE

Medical Devices Quality Management System of
MAF CLOTHING PRIVATE LIMITED

MAF CLOTHING PVT LTD UNIT-3,
Sy. No59/3, 59/4, Rajathadripura, Near K B Cross, Tiptur Taluk,
Tumkur District - 572114. Karnataka, India.

has been found to comply with

ISO 13485:2016

This certificate is applicable to the following scope:

MANUFACTURING AND SUPPLY OF SURGICAL MASKS, DUST MASK, GENERAL N95 RESPIRATOR, EN 149 FFP2 MASK, N95 FFP2 MASK, MEDICAL GOWNS, ALL PATIENT GOWNS, ISOLATION GOWN, SURGICAL GOWN, NON- SURGICAL GOWNS, PROCEDURAL GOWNS, OPERATING ROOM GOWNS, SURGICAL DRAPES, PPE KITS, PPE COVER ALL, CAP, SHOE COVER, FACE MASK, ALL BED SHEET, TROLLEY SHEET, OT SHEETS, DRAPES AND APRONS FOR RESEARCH AND PROCUREMENT RESEARCH ACROSS DIFFERENT INDUSTRY VERTICALS

Certificate No:: BCOMP202005003

Date of Initial Registration	19-05-2020
Surveillance Audit 01 On/Before	19-04-2021
Surveillance Audit 02 On/Before	19-04-2022
Certificate Expiry	18-05-2023



Authorized Signatory
BQC ASSESSMENT PRIVATE LIMITED
Website: www.bqcert.com, E-mail: info@bqcert.com, PK: + 91 9810618108

The validity of this certificate can be verified at www.bqcert.com or through info@bqcert.com
This certificate is the property of BQC Assessment Pvt. Ltd. and must be returned on request.



Scan this code with your smart phone
to verify the certificate



PARAMOUNT QUALITY CERTIFICATIONS

CERTIFICATE OF COMPLIANCE

This is to certify that the product/s manufactured by:

MAF CLOTHING PRIVATE LIMITED

MAF CLOTHING PVT LTD UNIT-3, SY. NO59/3, 59/4, RAJATHADRIPURA,
NEAR K B CROSS, TIPTUR TALUK, TUMKUR DISTRICT - 572114,
KARNATAKA, INDIA

has been independently assessed by PQC and found to comply with the
requirements of

GMP

(Good Manufacturing Practice)

Certification Scope:

MANUFACTURING AND SUPPLY OF SURGICAL MASKS, DUST MASK, GENERAL N95 RESPIRATOR, EN 149 FFP2 MASK, N95 FFP2 MASK, MEDICAL GOWNS, ALL PATIENT GOWNS, ISOLATION GOWN, SURGICAL GOWN, NON-SURGICAL GOWNS, PROCEDURAL GOWNS, OPERATING ROOM GOWNS, SURGICAL DRAPES, PPE KITS, PPE COVER ALL, CAP, SHOE COVER, FACE MASK, ALL BED SHEET, TROLLEY SHEET, OT SHEETS, DRAPES AND APRON

Certification Calendar:

Client Id: 740 Certificate No: 996/GMP/190520

Registered on: 19.05.2020 Issued on: 19.05.2020

Expires on: 18.05.2023

1st Surveillance on/before: 18.05.2021

2nd Surveillance on/before: 18.05.2022



Authorized Signatory

Validity of this certificate is subject to annual surveillance audits to be done successfully, on or before 365 days from date of this certificate.
This certificate remains the property of PQC & shall be returned immediately upon request.
27, Old Gloucester Street, London, WC1N 3AX, United Kingdom. Email: info@pqc.in, www.pqc.in



GOLD CERTIFICATE OF COMPLIANCE

MAF Clothing Pvt. Ltd. – Unit III

WRAP #: 125461

Certification Period: June 5, 2020 to June 5, 2021

Facility Address: Site No. 59/3, 59/4, Rajahadripura
Near K.B. Cross, Tiptur Taluk
Tumkur District, Karnataka
India 572114

Production Processes: Fabrics Receipt, Cutting, Stitching, Finishing, Ironing, Packing, and Dispatch

Sample Size: 35

Average Weekly Hours in Periods Reviewed: August 2019: 45 November 2019: 45 March 2020: 45

Please refer to the full audit report for details.



Avedis H. Seferian
President & CEO



Charles C. Masten
Chairman

Subject to the terms and conditions of the WRAP Certification Program and full compliance with the WRAP Production Principles