



## Y-CURE Y44 Series Respirator Face Mask - Technical Data

### Description:

**Y-Cure Y44** is the first Member of N95 Respirator Face Mask Series introduced by Frabon India Tech Solutions Ahmedabad Gujarat India Based Company

➤ 5 Layer Material Used:

Material: Polypropylene Non-Woven Fabric - Virgin Grade

1. First Layer: 50 GSM Spun Bond Material (White Color)
  2. Second Layer: 25 GSM Meltblown Filter (White Color)
  3. Third Layer: 50 GSM Spun Bond Material (White Color)
  4. Fourth Layer: 25 GSM Meltblown Filter (White Color)
  5. Fifth Layer: 25 GSM Spun Bond Material (White Color)
- Nose Clip – Plastic Welded or Aluminum
- Filter – 2 Layer of 25 GSM Meltblown Filter
- N95 Face Mask Body Size: 15 cm X 10 cm
- Ear Loop – Welded
- Shape – Arrow Dynamic – Flat & Fit to Face

### Certifications:

1. ISO 9001-2015
2. ISO 13485- 2006
3. ISO 16603 -2004
4. CE – Certificate of Compliance
5. EN 149 - 2001 FFP2, FFP3

### SITRA – Government of India Approved Lab Test Reports:

1. Bacterial Filtration Efficiency (BFE) of test specimen (%): **99.8 – FFP2, FFP3 Standard**
2. ASTM F1862/F1862M-13 – Pass
3. ASTM F2299/F2299M-03 (2010) Particulate Filtration Efficiency at 0.3 Microns (PFE) **97.45%**

## Frabon India Tech Solutions

107, Abhijeet 1Mithakhali Six Roads Circle Mithakhali Ahmedabad - 380 009

Phone: +919265298784 | Email: [cbo@frabon.com](mailto:cbo@frabon.com) | [cbo@y-cure.in](mailto:cbo@y-cure.in) | [www.y-cure.in](http://www.y-cure.in)

Product Real Picture:



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## Disposal:

Contaminated Products Should Be Disposed as Hazardous Waste In Accordance With Local or Hospital Regulations.

## Proper Fit Check:

- ✓ Cover the front of the respirator with both hands being careful not to disturb the respirator.
- ✓ Exhale sharply into the respirator.
- ✓ If air leaks around the nose, readjust the nose clip to eliminate leakage. Repeat the above fit check

## User Instructions:



1  
Pull open mask  
to fit the face



2  
Gently press the  
nose clip to ensure  
no air leakage



3  
Pull down the mask  
to ensure that it is  
sealed around

## ⚠ WARNING

This N95 Respirator helps Protect against Certain Particles Misuse can Result in Sickness or Death



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## MSME Registration:

4/27/2020

<https://udyogaadhaar.gov.in/UA/PrintAcknowledgement.aspx>

भारत सरकार Govt. of India		MSME	
सूक्ष्म, लघु और मध्यम उद्यम मंत्रालय MINISTRY OF MICRO, SMALL & MEDIUM ENTERPRISES		सूक्ष्म, लघु और मध्यम उद्यम MICRO, SMALL & MEDIUM ENTERPRISES	
<b>A</b>		Type of Enterprise	Micro Small Medium
		Manufacturing	A B C
		Services	D E F
		UAM No.	<b>GJ01D0150697</b>

**Udyog Aadhaar Registration Certificate**

Udyog Aadhaar Number: GJ01D0150697

Name of Enterprise: FRABON INDIA TECH SOLUTIONS

Location of Plant Details

SN	Flat/Door/Blook No.	Name of Premises/Building Village	Road/Street/ Lane	Area/Locality	City	Pin	State	District
1	604	ANIKET COMPLEX	C G ROAD	NAV/ARANGPURA	AHMEDABAD	380009	GUJARAT	AHMADABAD
2	22	Shivalaya Industrial Estate	Odhav Ring Road Circle	Behind Safari Hotel, Odhav	Ahmedabad	382415	GUJARAT	AHMADABAD

Official Address of Enterprise: 604, ANIKET COMPLEX , CG ROAD NAVRANGPURA

District: AHMADABAD State: GUJARAT PIN: 380009

Mobile No: 7798917699 Email: frabonindia@gmail.com

Date of commencement: 26/10/2018

Major Activity: MANUFACTURING

Enterprise Type: Micro

Previous Registration details-if any: ::

National Industry Classification Code

SN	NIC 2 Digit	NIC 4 Digit	NIC 5 Digit Code	Activity Type
1	13 - Manufacture of textiles	1399 - Manufacture of other textiles n.e.c.	13999 - Manufacture of other textiles/textile products n.e.c.	Manufacturing
2	63 - Information service activities	6311 - Data processing, hosting and related activities	63119 - Other data processing, hosting and related activities n.e.c.	Services

Acknowledgement: Date of Filing: 18/05/2019 Date of Printing: 27/04/2020

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MyMeme Mobile App (Beta Version) is available now for download. <https://play.google.com/store/apps/details?id=com.mymeme>



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ISO 13485-2016 :

Certificate



## Certificate of Compliance

This is to certify that

### FRABON INDIA TECH SOLUTIONS

107, ABHIJEET 1, MITHAKHALI SIX ROAD, NAVARANGPURA,  
METHAKHALI AHMEDABAD- 380016, GUJARAT, INDIA

has been assessed and certified by Quality Veritas Certification Limited (UK) as meeting the requirements of

## ISO 13485: 2016

### Quality Management System for Medical Devices

For the following activities

EXPORT & SUPPLY Y-CURE BRANDED SURGICAL DISPOSABLE FACE MASK, DISPOSABLE CAP, DISPOSABLE SHOE COVERS, DISPOSABLE APRON, DISPOSABLE GLOVES, DISPOSABLE COVERALL, GOWN, DISPOSABLE BSB SHEET, DISPOSABLE GARBAGE BAGS, DISPOSABLE DRAPES, DISPOSABLE PPE KIT, WET WIPES FOR ADULTS, WET WIPES FOR BABY, DISPOSABLE BABY DIAPER, DISPOSABLE ADULT DIAPER, DISPOSABLE MAT, DISPOSABLE PILLOW COVER, DISPOSABLE BAO SHEET, DISPOSABLE APRON, DISPOSABLE CLOTHES, DISPOSABLE SWEATS, DISPOSABLE PANTS, BOUJANT CAP, SHOWER CAP, SURSTON CAP, SURSTON GOWN, SURSTON COVERALL, MOPP, COTTON BALLS

Date of Registration	: 08 March 2020
1st Surveillance Due	: 07 March 2021
2nd Surveillance Due	: 07 March 2022
Certificate Expiry (subject to the ongoing monitoring in accordance with the ISO 13485 standard)	: 07 March 2023

Certificate No - 2003086056

To Verify this certificate please visit at [www.qvcert.co.uk](http://www.qvcert.co.uk)




**Quality Veritas Certification Limited**  
Validity of this certificate is subject to annual surveillance audits done successfully  
 Tel: 0203 086056 Fax: 0203 086057 | Quality Veritas Certification Limited, Suite 48, Hatton Garden, London, EC1N 8PN, UK  
 Email: [info@qvcert.co.uk](mailto:info@qvcert.co.uk) Website: [www.qvcert.co.uk](http://www.qvcert.co.uk)

**Suite 48, 88-90 Hatton Garden, London, EC1N 8PN, UK**

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# Certificate of Compliance – CE

شهادة

ZERTIFIKAT

CERTIFICATO

CERTIFICADO

CERTIFICATE



## Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directive 93/42/EEC according to Medical Device And Personal Protective Equipment Directive (PPE).

Certificate No.: CE-2020-FITS-121 90

**Manufacturer**  
**Name :** FRABON INDIA TECH SOLUTIONS  
**Address :** 107, ABHIJEET 1, MITHAKHALI SIX ROAD, NAVARANGPURA, MITHAKHALI, AHMEDABAD - 380009 (GUJARAT) (INDIA)

**Product :** EXPORT & SUPPLY Y-CURE BRANDED SURGICAL DISPOSABLE FACE MASK, 305, DISPOSABLE CAP, DISPOSABLE SHOES COVER, DISPOSABLE APRON, DISPOSABLE GLOVES, DISPOSABLE COVERALL, GOWN, DISPOSABLE BED SHEET, DISPOSABLE GARMENTS, DISPOSABLE DRAPES, DISPOSABLE PPE KIT, HYI KIT, DELIVERY KIT & OPHTHALMIC BLADES, WET WIPES FOR ADULTS, WET WIPES FOR BABY, DISPOSABLE BABY DIAPER, DISPOSABLE ADULT DIAPER, DISPOSABLE MAT, DISPOSABLE PILLOW COVER, DISPOSABLE BED SHEET, DISPOSABLE APRON, DISPOSABLE CLOTHES, DISPOSABLE SHIRTS, DISPOSABLE PANTS, BOUFFANT CAP, SHOWER CAP, SLINGDON CAP, SURGICEM GOWN, SURGICEM COVERALL GOWN, COTTON BALES

The Certification body has performed an audit of the above testing and verified the design system, manufacture and final inspection of the certified product. The Product specification has been assessed, approved and is subject to continuous surveillance according to the directives 93/42/EEC according to MDD & PPE.

**This certificate is issued under the following conditions:**

1. Fulfilled standard requirements as per implementation of suggested standards.
2. The certificate remains valid until the manufacturing conditions are changed.
3. The certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant Standard testing performance, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown can be used, under the responsibility of the unit, after completion of a EU Declaration of conformity and compliance with all relevant EU Directive.

Validity of this certificate can be verified at [www.gacb.us](http://www.gacb.us)

Date of Certification: 12 <sup>th</sup> Apr 2020	1 <sup>st</sup> Surveillance Due: 11 <sup>th</sup> Apr 2021
Date of Recertification: 11 <sup>th</sup> Apr 2023	2 <sup>nd</sup> Surveillance Due: 11 <sup>th</sup> Apr 2022

(Subject to the company maintaining its system To the required standard)

CE

  
 Authorized Signatory



Validity of this Certificate is subject to Annual Surveillance audits done successfully  
 This certificate remains the property of QCS and must be returned whenever demanded QCS is an independent system product and personal assessment body QCS is accredited by Global Accreditation Certification Board (GACB)  
 US OFFICE: Maryland Avenue, SW Washington, D.C. -20202  
[info@qscertgroup.com](mailto:info@qscertgroup.com) | [www.qscertgroup.com](http://www.qscertgroup.com)

## Frabon India Tech Solutions

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EN149-2001 FFP2, FFP3

شهادة ■ ZERTIFIKAT ■ CERTIFICATO ■ CERTIFICADO ■ CERTIFICATE

  
**Certificate of Compliance**  
This is to certify that

**FRABON INDIA TECH SOLUTIONS**  
ADDRESS: 107, ABHIJET 1, MITHAKHALI SIX ROAD, NAVARANGPURA,  
MITHAKHALI, AHMEDABAD - 380009 (GUJARAT) (INDIA)

Has been assessed by QCS and found to be  
Comply with the requirements of:

**EN 149:2001**  
"RESPIRATORY PROTECTIVE DEVICES(FFP2, FFP3)"

For the following scope:

*"MANUFACTURING, EXPORT & SUPPLY OF PERSONAL PROTECTION EQUIPMETN (PPE)  
KIT, Y-CURE BRANDED N95 PROTECTIVE FACE MASK, KN95 PROTECTIVE FACE MASK,  
N95 RESPIRATOR FACE MASK, KN95 RESPIRATOR FACE MASK, 3 PLY 3 LAYER FACE  
MASK, 3 PLY 4 LAYER FACE MASK, REUSABLE PROTECTIVE FACE MASK,  
WASHABLE PROTECTIVE FACE MASK*

Certificate Number: QCS-2020-FITS-26612

To verify this certificate please visit at [www.gacb.us](http://www.gacb.us)

Date of Certification: 26<sup>th</sup> May 2020  
Date of Recertification: 25<sup>th</sup> May 2023  
(Subject to the company maintaining its system  
To the (standard)

1<sup>st</sup> Surveillance Due: 25<sup>th</sup> May 2021  
2<sup>nd</sup> Surveillance Due: 25<sup>th</sup> May 2022

  
GACB  
GLOBAL ACCREDITATION CERTIFICATION BOARD

  
Authorized Signatory



Validity of this Certificate is subject to Annual Surveillance audits done successfully  
This certificate remains the property of QCS and must be returned whenever demanded QCS is an independent  
system product and personal assessment body QCS is accredited by  
Global Accreditation Certification Board (GACB)  
US OFFICE: Maryland Avenue, SW Washington, D.C. -20202  
[info@qcs-certgroup.com](mailto:info@qcs-certgroup.com), [www.qcs-certgroup.com](http://www.qcs-certgroup.com)

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# SITRA GOVERNMENT LAB REPORT : BFE 99.8%



**THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION**

**CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES**

**Physical, Chemical & Biological Testing Laboratories**

(ISO/IEC 17025 NABL ACCREDITED)

13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA



Cert. Number:TC-4944

Test Report No : M2001077	ULR: TC694420700000775F	Report Date : 02-06-2020
Frabon India Tech Solutions		Ref: DT 13.05.2020

**Test Name :** Bacterial Filtration Efficiency - N95 and N99 Mask STANDARD TEST METHOD FOR EVALUATING THE BACTERIAL FILTRATION EFFICIENCY (BFE) OF MEDICAL FACE MASK MATERIALS, USING A BIOLOGICAL AEROSOL OF STAPHYLOCOCCUS AUREUS

**Test Condition:**

Test Organisms Used : *Staphylococcus aureus* ATCC 6538  
 Inoculum size :  $5 \times 10^5$  CFU/mL  
 Media used : Tryptic soya agar  
 Dilution medium used : Peptone water  
 Incubation conditions : 37°C for 24 h

**Observation :**

	M2001077-1 Described by the customer : <b>Face Mask: N95 FFP2 Compatible NIOSH FACE MASK</b>
Area of test specimen	Face mask 10 x 10 cm
Sample exposure side	Face side
Flow rate of aerosol	28.5 L / min
Mean particle size of challenging aerosol	3.0 ± 0.3 micron
Average plate count of positive control	1783
Average plate count of negative control	0
BFE of test specimen (%)	99.8
<p><b>Result :</b> : The sample showed 99.8 % bacterial filtration efficiency against <i>Staphylococcus aureus</i> ATCC 6538 when tested according to ASTM F 2101 test method. Disclaimer: The test performed (as above) is specific to surgical face mask. SITRA does not have facility for evaluating the performance of N 95 and N 99 respirator masks. Necessary care may be taken by the end user while interpreting the above results for the intended use.</p>	

- End of Report -

Authorized Signatory

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## SITRA GOVERNMENT LAB REPORT : PFE 97.45%



### THE SOUTH INDIA TEXTILE RESEARCH ASSOCIATION

CENTRE OF EXCELLENCE FOR MEDICAL TEXTILES

Physical, Chemical & Biological Testing Laboratories

(ISO/IEC 17025 NABL ACCREDITED)

13/37, Avinashi Road, Aerodrome Post, Coimbatore - 641 014, INDIA



Cert. Number:TC-6944

Frabon India Tech Solutions, Ref : Letter dt 13.05.2020

ULR: TC684420600003943P

(Sample Tested at : R.H.65% +/- 2% and Temp. 21 Degree C +/- 1 Degree C)

Differential Pressure** IS 16289:2014 Annexure C Pa/cm*	P2005329-1 Described by the Customer : Y-Cure Face Mask 39.0
Splash Resistance ASTM F1862/F1862M-13 Result at 160mmHg	P2005329-1 Described by the Customer : Y-Cure Face Mask Pass
Particulate Filtration Efficiency at 0.3 Microns ASTM F2299/F2299M-03 (2010) Percentage	P2005329-1 Described by the Customer : Y-Cure Face Mask 97.45

- All Certification & Reports are available on our website for Review
- THIS PRODUCT IS 100% MADE IN INDIA MADE FOR INDIA

## Frabon India Tech Solutions

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