

NITRILE

POWDER FREE EXAMINATION GLOVES
PUDERFREI UNTERSUCHUNGSHANDSCHUHE

NON-STERILE
AMBIDEXTROUS
SINGLE USE ONLY



GENTLE TOUCH
DISPOSABLE
GLOVES

S M L XL

WHITE BLUE BLACK

100 PCS

OPEN HERE



FIRST GLOVE

POWDER FREE NITRILE EXAMINATION GLOVES
PUDERFREIE NITRIL-UNTERSUCHUNGSHANDSCHUHE
GANTS D'EXAMEN EN NITRILE SANS POUDRE
GUANTES DE EXAMEN DE NITRILE SIN POLVO
GUANTI DA ESPLORAZIONE IN NITRILE SENZA POLVERE

FIRST GLOVE
NITRILE
100 PCS

Nitrile gloves, powder free, 100 units. Usage Recommendations: Restriction of use for a limited time, before use inspect the glove for any defect or imperfection. It should not be used when there is a risk of entrapment by moving parts of machines. It protects the user against microorganisms and viruses. Chemical resistance can be different if the chemical is used in a mixture. It has been evaluated under laboratory conditions from samples taken only from the palm. PPE should never be used against other than mentioned risks.

Mit Handschuhe zu jeder Zeit, 100 Einheiten. Verwendungsempfehlungen: Nutzungsbeschränkung für eine begrenzte Zeit. Überprüfen Sie den Handschuh vor Gebrauch auf etwaige Mängel. Es sollte nicht verwendet werden, wenn die Gefahr besteht, dass sich bewegende Maschinenanteile verklemmen. Es schützt den Benutzer vor Mikroorganismen und Viren. Die chemische Beständigkeit kann unterschiedlich sein, wenn die Chemikalie in einer Mischung verwendet wird. Sie wurde unter Laborbedingungen anhand von Proben bewertet, die nur aus der Handfläche entnommen wurden. PSA sollten niemals gegen andere als die oben genannten verwendet werden.

Guantes de nitrilo sin polvo, 100 unidades. Recomendaciones de uso: restricción d'uso por un periodo de tiempo limitado, prima dell'uso ispeziona il guanto per qualsiasi difetto o imperfezione. Non deve essere utilizzato quando esiste il rischio di intrappolamento dovuto allo spostamento di parti delle macchine. Protegge l'utente da microrganismi e virus. La resistenza chimica può essere diversa se la sostanza chimica è utilizzata in una miscela. È stata valutata in condizioni di laboratorio da campioni prelevati solo dal palmo. I DPI non dovrebbero mai essere usati contro altri da quelli sopra menzionati.

Guantes de nitrilo sin polvo, 100 unidades. Recomendaciones de uso: Restricción de uso por tiempo limitado, antes de su uso, inspeccione el guante para detectar cualquier defecto o imperfección. No debe usarse cuando exista riesgo de quedar atrapado por las partes móviles de las máquinas. Protege al usuario contra microorganismos y virus. La resistencia química puede ser diferente si el producto químico se utiliza en una mezcla. Se ha evaluado en condiciones de laboratorio a partir de muestras tomadas únicamente de la palma. El PPE nunca debe usarse contra otros que no sean los mencionados.

Guants en nitril sans poudre, 100 unités. Recommandations d'utilisation: restriction d'utilisation pour une durée limitée, avant utilisation inspecte le gant pour tout défaut ou imperfection. Il ne doit pas être utilisé en cas de risque de piégeage par les mouvements des machines. Il protège l'utilisateur contre les micro-organismes et les virus. La résistance chimique peut être différente si le produit chimique est utilisé dans un mélange. Il a été évalué dans des conditions de laboratoire à partir d'échantillons prélevés uniquement sur la paume. Les EPI ne doivent jamais être utilisés contre d'autres.



FIRST GLOVE
NITRILE

LOT: 122820
12/2020
11/2025
Conforms to EN455 - 1/2
EN374 - 1/2
AQL = 1.5
In accordance with 93/42/EEC
& 89/686/EEC

LOT: 122820
12/2020
11/2025
Conforms to EN455 - 1/2
EN374 - 1/2
AQL = 1.5
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PUDERFREI UNTERSUCHUNGSHANDSCHÜHE

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GENTLE TOUCH
DISPOSABLE
GLOVES

S M L XL
WHITE BLUE BLACK
10 x 100
1000 PCS

FIRST GLOVE
NITRILE
POWDER FREE EXAMINATION GLOVES
PUDERFREI UNTERSUCHUNGSHANDSCHÜHE

CARTON NO.:

Packed by:
SafeFirst India Rubber Products Pvt Ltd
Plot No. 189, SE-2,
Kulkarni, Andhra Pradesh, 515016
www.safefirstindia.com

LOT	122820
	12/2020
	11/2025

Conforms to EN455 - 1/2
EN374 - 1/2
AQL = 1.5
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FIRST GLOVE
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POWDER FREE EXAMINATION GLOVES
PUDERFREI UNTERSUCHUNGSHANDSCHUHE

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Conforms to EN455 - 1/2
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LOT	122820
	12/2020
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NON-STERILE
AMBIDEXTROUS
SINGLE USE ONLY



GENTLE TOUCH
DISPOSABLE
GLOVES

10 x 100
1000 PCS

NITRILE
POWDER FREE EXAMINATION GLOVES
PUDERFREI UNTERSUCHUNGSHANDSCHUHE

FIRST GLOVE

ULR -TC-617621000001976

TEST REPORT

Report No. : CH:TX:1242001977

DATE : 22/01/2021



SAFESHIELD INDIA RUBBER PRODUCTS PRIVATE LIMITED

PLOT NO 16 B CSEZ KAKKANAD COCHIN, COCHIN SPECIAL ECONOMIC ZONE

Kochi-682037

IN

CONTACT PERSON : ANIKUMAR P C

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
POWDER FREE NITRILE EXAMINATION GLOVES

COLOUR BLUE

STYLE NO. AMBIDEXTROUS

ARTICLE NO. 122820

END USE MEDICAL PURPOSE

FIBRE CONTENT SYNTHETIC RUBBER LATEX(NITRILE)

CUSTOMER

COUNTRY OF DESTINATION AUSTRIA

COUNTRY OF ORIGIN INDIA

PHOTO APPENDIX.



SAMPLE RECD ON

18/01/2021

TESTING PERIOD : 21/01/2021 - 22/01/2021

Summary of Test Results/Conclusion

Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 420:2003+A1.2009	Protective gloves - General requirements	
	Dexterity	Performance level 5
EN ISO 374-4:2019	Resistance to Degradation by Chemicals	
	Methanol	Refer results.

Per pro SGS India Private Ltd.



R. GANESAN
SECTION INCHARGE

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

ULR -TC-617621000001976

TEST REPORT

Report No. : CH:TX:1242001977

DATE : 22/01/2021



RESULTS

EN 420 : 2003+A1: 2009 Protective Gloves – General requirements and test methods

Clause	Test Name	Result				Average	Standard sizing
5.2	Dexterity Smallest Pin Diameter (mm)	5	5	5	5	5	Performance level 5

EN ISO 374-4:2019 Protective Gloves against Chemicals and Micro Organisms – Determination of resistance to degradation by chemicals

Chemical / CAS NO	Exposure Duration	Test Results		Observation
		Percentage change in puncture resistance		
Methanol 67-56-1	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Moderate swelling
		1	57.6	
		2	56.4	
		3	58.1	
		Mean	57.4	
		Standard Deviation	0.917	

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

ULR -TC-617620000043110

TEST REPORT

Report No. : CH:TX:1142043221

DATE : 29/12/2020

SAFESHIELD INDIA RUBBER PRODUCTS PRIVATE LIMITED
PLOT NO 16 B CSEZ KAKKANAD COCHIN, COCHIN SPECIAL ECONOMIC ZONE
Kochi-682037
IN
CONTACT PERSON : ANIKUMAR P C

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION	GLOVES
COLOUR	POWDER FREE NITRILE EXAMINATION GLOVES
STYLE NO.	BLUE
ARTICLE NO.	AMBIDEXTROUS
END USE	122820
FIBRE CONTENT	MEDICAL PURPOSE
BUYER'S NAME	SYNTHETIC RUBBER LATEX(NITRILE)
BUYING HOUSE	
COUNTRY OF DESTINATION	
PHOTO APPENDIX.	



SAMPLE RECD ON

16/12/2020

TESTING PERIOD : 29/12/2020 - 29/12/2020

Summary of Test Results/Conclusion

Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 455-1:2000	Medical gloves for single use	
	Freedom from holes	Pass
EN 455-2:2015	Dimensions	Pass

Per pro SGS India Private Ltd.



R. GANESAN

SECTION INCHARGE

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com



RESULTS

MEDICAL GLOVES FOR SINGLE USE - DIMENSIONS EN 455-2:2015 (Method:4.2 & 4.3)

	Dimension (mm) Size : Small		Dimension (mm) Size : Medium		Dimension (mm) Size : Large		Dimension (mm) Size : Extra Large	
	Length	Width	Length	Width	Length	Width	Length	Width
Specimen -1	245	87	248	96	253	106	243	115
Specimen -2	241	85	250	95	255	104	241	114
Specimen -3	244	85	247	96	255	105	244	116
Specimen -4	246	84	249	94	254	105	244	115
Specimen -5	244	85	249	95	255	104	243	113
Specimen -6	244	87	251	95	253	106	243	114
Specimen -7	246	87	250	94	252	106	242	115
Specimen -8	243	84	253	96	250	104	245	114
Specimen -9	243	83	249	95	255	106	243	116
Specimen -10	246	86	252	95	254	105	242	116
Specimen -11	244	84	250	96	253	104	241	115
Specimen -12	245	85	251	94	252	106	244	114
Specimen -13	243	86	249	95	254	105	241	115
Requirement	≥ 240	80 ± 10	≥ 240	95 ± 10	≥ 240	110 ± 10	≥ 240	≥ 110

MEDICAL GLOVES FOR SINGLE USE – FREEDOM FROM HOLES EN 455-1:2000 (Method:5.1)

Sample Size : 20 pcs
Number of non-confirming gloves: 4 pcs
Acceptable Number of non-confirming gloves: 7 pcs

Note : Sampling was carried out as per ISO 2859-1 AQL of 1.5, General inspection level 1 and sample code letter L.

***** End of report*****



CERTIFICATE OF APPROVAL

Issued by Indian Register Quality Systems
(A Division of IRCLASS Systems and Solutions Private Limited)

CERTIFICATE

Organisation: Safeshield India Rubber Products Pvt. Ltd.

Address: Plot No 16B, CSEZ, Kakkanad,
Cochin-682037, Kerala, India

This is to certify that the organization has been assessed and found to follow the
Good Manufacturing Practices as per

WHO Guidelines: WHO Good Manufacturing Practices for
Pharmaceutical Products: Main
Principles (Annex 2)

For the Scope: Manufacture and Dispatch of
Powdered & Powder Free, Sterile &
Non Sterile Latex Surgical,
Gynaecological & Examination Gloves

Certificate No.: IRQS/200300323

Original Certification Date: 29/06/2020

Current Date of Granting: 29/06/2020

Expiry Date : 28/06/2023



Indian Register Quality Systems

Shashi Nath Mishra
Head IRQS

This approval is subject to continued satisfactory maintenance of the Good Manufacturing Practice Systems of the organization to the above Standard, which will be monitored by IRQS. Condition Overleaf COA/IRQS/GMP/Rev 00

Head Office: 52A, Adi Shankaracharya Marg, Opp. Powai Lake, Powai, Mumbai - 400 072, India.

Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC Class I.

Certificate No.: CE-11161

Manufacturer

Name : **Safeshield India Rubber Products Pvt. Ltd.**
Address : **Plot No.16B, CSEZ, Kakkanad, Cochin-682037, Kerala, India.**
Product Name : **Nitrile Examination Gloves Powder Free
Latex examination Gloves- Powdered
Latex examination Gloves-Powder Free
Vinyl Examination Gloves-Powder Free
3 Ply & 4 Ply Surgical Facemask**

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC class I.

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.

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 test report of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	04th June 2020
1 st Surveillance Audit Due	03rd June 2021
2 nd Surveillance Audit Due	03rd June 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	03rd June 2023

Daniel..

Authorised Signatory





Certificate No. MD-QMS/91/R/2646

This is to certify that

Safeshield India Rubber Products Pvt. Ltd.

Plot No. 16B, CSEZ, Kakkanad, Cochin – 682 037, Kerala, India

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

Design, Manufacture and Sales of Sterile and Non-Sterile Surgical and Gynecological Gloves in Powdered and Powder Free Form

Initial Certification : 08/07/2019
Valid until : 07/07/2022



UK



Authorised Signatory



This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>. The authenticity of this document may be re-affirmed by writing to certification@zenith-worldwide.com. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.



Accreditation Body: Accreditation Service for Certifying Bodies (Europe) Ltd.
6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.
www.ascb.co.uk

Issuing Authority: Zenith Quality Assessors Pvt. Ltd. - MSCD001
306, 4th Floor, Sai Apex, Vimannagar, Pune-411014, Maharashtra, India
www.zenith-worldwide.com

CERTIFICATE

The Certification Body
of TÜV SÜD South Asia Private Limited

certifies that



Safeshield India Rubber Products Private Ltd.
Plot No. 16.B, CSEZ, Kakkanad Cochin, Kerala - 682 037, INDIA

has implemented a Quality Management System
in accordance with **ISO 9001:2015**

For Scope of

**TREATMENT, POWDER REMOVAL, PACKAGING & MARKETING OF
STERILE AND NON-STERILE LATEX SURGICAL AND EXAMINATION
GLOVES IN POWDERED AND POWDER FREE FORM**

The certificate is valid From **2020-08-19** until **2023-08-18**

Subject to successful completion of annual periodic audits

The present status of this Certificate can be obtained on www.tuv-sud.in

Further clarifications regarding the scope of this certificate may be obtained by consulting the certification body

Certificate Registration No. **99 100 12728**

Date of Initial certification : **2011-08-19**



Certification Body
of TÜV SÜD South Asia Private Limited, **Mumbai**
Member of TÜV SÜD Group

