

ROSENBERG[®]

FULL PRESENTATION



THE
GLOVES
THAT
MAKE THE
WORLD
SAFER



Nitrile Blue Medical Examination Gloves

Chemical resistant EN ISO 374-1:2016
Protection against virus ISO 374-5:2016

The ROSENBERG Nitrile Blue medical examination gloves are high performing 5mil thick powder-free blue colored ambidextrous gloves that are chemical resistant under EN-374 and intended for use in medical field to: protect patient and user from crosscontamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material.



Rosenberg is a registered trademark produced and distributed by Rosenberg GmbH.

ROSENBERG®

Disposable Examination Gloves

Nitrile Blue

Medical Examination Gloves

The ROSENBERG Nitrile Blue medical examination gloves are high performing 5mil thick powder-free blue colored ambidextrous gloves that are intended for use in medical field to: protect patient and user from crosscontamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. This examination glove product conforms under International, American and European standards specific to: ASTM D6319, EN374 and EN455.



EN 455
EN 420
EN 374

EN 374-1:2016/Type B



EN 374-5:2016



AQL
1.5



Sizes Available

- Small
- Medium
- Large
- X-Large

5 Mil
Thickness

	mils	mm
Palm Thickness	5.0min	0.13min
Finger Thickness	5.0min	0.13min
Cuff Thickness	5.0min	0.13min

ROSENBERG[®]

Disposable Examination Gloves

Nitrile Blue

Medical Examination Gloves



These gloves are 100% Nitrile (Acrylonitrile), and are designed to provide an excellent biological barrier and good resistance to bacteria, fungi, viruses and a variety of chemicals found in typical medical and laboratory environments. It is recommended to check the glove's resistance to the chemical used in the intended application and conditions of the workplace may differ from the test conditions for the nitrile glove. When used, protective gloves may provide less resistance to the dangerous chemical due to the degradation of the material. Therefore, it is recommended to check the glove's resistance to the chemical used in the intended application. For complete chemical, degradation and the most important factors to consider in selection of chemical resistant gloves.

5 Mil Thickness

5.0mm Palm Thickness
5.0mm Finger Thickness
0.13mm Cuff Thickness

240 mm Max Length

ISO 15184
EN 374-2016
EN 374-2016/Type B
MD
FDA 510(k)
ASTM
PPE
MDD

ROSENBERG[®]

Disposable Examination Gloves

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

5 Mil Thickness

100 Pieces by weight

Textured Fingertips
EN 374-2016

CE
VIRUS
FDA 510(k)
ASTM
PPE (EU 2014/53) CAT III
MDD (EU 93/42/EEC) CLASS III

Nitrile Blue

XL L M S

POWDER
LATEX

Schutz vor gefährlichen Chemikalien und Mikroorganismen

Diese Handschuhe bestehen zu 100% aus Nitril (Acrylonitril) und bieten eine hervorragende biologische Barriere und eine gute Resistenz gegen Bakterien, Pilze, Viren und eine Vielzahl von Chemikalien, die in typischen medizinischen und industriellen Umgebungen vorkommen. Es wird empfohlen zu überprüfen, ob die Handschuhe für den vorgesehenen Verwendungszweck geeignet sind, da die Bedingungen am Arbeitsplatz je nach Temperatur, Abrieb und Verschlechterung von der Typprüfung abweichen können. Bei Verwendung können Schutzhandschuhe aufgrund von Änderungen der physikalischen Eigenschaften eine geringere Barrierefunktion gegenüber der gefährlichen Chemikalie bieten. Bewegungen, Verbleiben, Verschlechterung durch chemischen Kontakt usw. können die tatsächliche Verwendungsdauer erheblich verkürzen. Bei atzenden Chemikalien kann der Abbau der wichtigste Faktor bei der Auswahl chemikalienbeständiger Handschuhe sein.

5 Mil Thickness

100 Pieces by weight

Textured Fingertips
EN 374-2016

CE
VIRUS
FDA 510(k)
ASTM
PPE (EU 2014/53) CAT III
MDD (EU 93/42/EEC) CLASS III

Nitrile Blue

XL L M S

POWDER
LATEX



ROSENBERG[®]

Disposable Examination Gloves

MD LOT RB123456 2021-02-01 2025-02-01

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

5 Mil Thickness

100 Pieces by weight

Textured Fingertips
EN 374-2016

CE
VIRUS
FDA 510(k)
ASTM
PPE (EU 2014/53) CAT III
MDD (EU 93/42/EEC) CLASS III

Nitrile Blue

XL L M S

POWDER
LATEX



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Rosenberg Disposable Nitrile Examination Gloves.
Rosenberg Gloves, the Rosenberg Logo and Box are Trademarks of the Rosenberg Group and is registered in Germany and in other countries by Patent.

Rosenberg Disposable Nitrile Examination Gloves Manufactured by:
ROSENBERG GMBH
Email: info@rosenberg-group.de
Web: www.rosenberg-group.de

Key Features



Protective against dangerous chemicals and microorganisms

These gloves are 100% Nitrile (Acrylonitrile), and are designed to provide an excellent biological barrier and good resistance to bacteria, fungi, viruses and a variety of chemicals found in typical medical and industrial environments. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

*The range of chemicals tested and Type (A/B/C) under EN ISO 374-1:2016 may vary in for this product in different markets. For further information on chemical resistance, please contact us on: info@rosenberg-group.de

EN 374-1:2016/Type B



KPT

EN 374-5:2016



VIRUS



Nitrile Blue

Medical Examination Gloves

Approved Standards & Conformity

These gloves have been tested and approved in accordance with the requirements of International, American and European standards specific to:



MDD classification & compliance: Council Directive 93/42/EEC

Gloves are classified as class I Medical Device as per Annex VIII of the Medical Device Regulation 2017/745 and comply to standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

EN 455-1:2000 Medical gloves for single use
Pt. 1: Requirements and testing for freedom from holes

EN 455-2:2015 Medical gloves for single use
Pt. 2: Requirements and testing for physical properties

EN 455-3:2015 Medical gloves for single use
Pt. 3: Requirements and testing for biological evaluation

EN 455-4:2009 Specification for nitrile examination gloves for medical application



PPE classification & compliance: PPE Directive (EU) 2016/425 (formerly 89/686/EEC)

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 374-3 2015, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

EN 420:2003 Protective gloves - general requirements and test methods

EN ISO 374-1:2016 Protective gloves against dangerous chemicals and microorganisms
Pt. 1: Terminology and performance requirements for chemical risks

EN 374-2:2014 Protective gloves against dangerous chemicals and microorganisms
Pt. 2: Determination of resistance to penetration

EN 374-3:2015 Protective gloves against chemicals and micro-organisms.
Pt. 3: Determination of resistance to permeation by chemicals

EN 16523-1:2015 Determination of material resistance to permeation by chemicals
Pt. 1: Permeation by liquid chemical under conditions of continuous contact

EN 374-4:2013 Protective gloves against chemicals and micro-organisms
Pt. 4: Determination of resistance to degradation by chemicals

EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms
Pt. 5: Terminology and performance requirements for micro-organisms risks



ASTM-D6319: Standard Specification for Nitrile Examination Gloves for Medical Application

Manufactured in FDA-registered facilities utilizing an FDA-registered 510(k) formulation. Meets US government 21-CFR specifications and the current specifications listed under the ASTM specification D6319, Standard for Nitrile Gloves for Medical Application; acceptable for use in food and pharmaceutical applications..

ASTM D 6319

Specification for nitrile examination gloves for medical application

Nitrile Blue

Medical Examination Gloves



Contact us for more information:
info@rosenberg-group.de

ROSENBERG[®]

TECHNICAL FILE NITRIL GLOVES



ROSENBERG	PRODUCER INFORMATION	Reg.Date	26.02.2021
		Rev.Date:	16.03.2021
		Rev. No	JS 16-3/RB21

FIRM NAME	ROSENBERG GMBH
AUTHORIZED NAME	Mr. Bora F. Akcal
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E-mail	<i>info@rosenberg-group.de</i>
Adresses	Zeilweg 44 60439 Frankfurt am Main / Germany
Tax Administration	Finanzamt Frankfurt am Main
Tax Administration Number	DE33 6134 295
Province	Frankfurt am Main
District	Hessen
Post Code	60439

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NITRILE GLOVES

People who are allergic to the protein contained in natural rubber extract are recommended to use Nitrile Gloves instead of latex gloves. Nitrile gloves are a kind of artificial latex and natural latex is not used in its production. Its raw material is acrylonitrile butadiene, a synthetic co-polymer. Nitrile gloves are powder-free and preferred for those with powder sensitivity / allergies. On the other hand, it is frequently used in workplaces where no powder is preferred in the area of use. It is 2-3 times more durable than latex gloves. It is much more resistant to tearing / punctures, and thanks to the roughness on the fingertips, it grips the place it touches better and does not slip. In addition, they are more resistant to a wide spectrum of chemicals than Latex gloves and are preferred by people who have frequent contact with chemicals in the work environment. There are blue, orange and black alternatives. The blue nitrile glove is mostly preferred by healthcare professionals, black nitrile gloves by food industry professionals, and orange nitrile gloves by chemical industry workers. The things you should pay attention to when purchasing these gloves, which are especially used in laboratories, are as follows:

- It should be in the complex designed glove group according to EN Guidelines.
- It should bear the CE 2777 conformity mark, meet the EN 420: 2003 and EN 374: 2016 standards, and be in CATEGORY III class.
- There should be symbols showing MD, CE or international standards on its packaging.
- Gloves should be made of 100% nitrile material and be powder-free.
- AQL value should be 1.5 on the packaging.
- Gloves must comply with EN 374/2, EN 374/3 standards.

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GLOVES USAGE INSTRUCTIONS

1. OBJECTIVE

1.1. To determine the methods of using gloves to reduce the risk of transmission of healthcare-associated infections from staff to patients, from patient to staff, or from one patient to another.

2. SCOPE

2.1. It covers the activities of all healthcare professionals in the hospital to use gloves properly.

3. RESPONSIBLE

3.1. All hospital staff involved in diagnosis, treatment and care applications are responsible for the implementation of this instruction. On behalf of the Chief Physician, the Infection Control Committee is responsible for the inspections related to the implementation of this instruction.

4. APPLICATION

4.1. Basic Principles

4.1.1. Gloves should not be used instead of hand washing.

4.1.2. Hands should be washed before and after wearing gloves.

4.1.3. Staff should be informed that wearing gloves does not provide complete protection against hand contamination.

4.1.4. Gloves should be removed as soon as the indication for wearing gloves has ceased.

4.1.5. Gloved hands should not be washed or applied with alcohol-based hand sanitizer.

4.1.6. In cases where the risk of infection is high, double layers of gloves (two gloves on top of each other) should be worn.

4.1.7. Gloves should be removed after caring for a patient.

4.1.8. The same glove should not be used for the care of more than one patient.

4.1.9. Two different attempts should never be made with the same glove.

4.1.10. Gloves should not be washed or reused.

4.1.11. Gloves should be changed when passing from the contaminated body area to the clean body area during patient care.

4.1.12. Gloves should be changed when passing from patient to patient.

4.2. Conditions to Wear Gloves

4.2.1. If there is a possibility of contact with blood, body fluids, secretions or mucous membranes or skin,

4.2.2. Prior to contact with instruments contaminated with respiratory secretions or respiratory secretions.

4.2.3. In contact with contaminated objects and environmental surfaces,

4.2.4. Before and after entering the rooms of patients who have been isolated,

4.2.5. When healthcare personnel have cuts, scratches and cracks,

4.2.6. When changing serum sets and inserting the blood set into the blood bag,

4.2.7. While taking blood

4.2.8. Cleaning places where blood and body fluids have been spilled,

4.2.9. Assisting the aspirated patient,

4.2.10. In every care given to the patient

4.3. Conditions to Wear Sterile Gloves

4.3.1. Sterile gloves should only be used for interventions on sterile areas of the body, open wounds and when the material used needs to be sterile.



EC Declaration of Conformity

We hereby **ROSENBERG GMBH** declare that, the following described product in our delivered version complies with the appropriate basic safety and health requirements of the (EU) 2016/425 Personal Protective Equipment Directive based on its design and type, as brought into circulation by us. In case of alteration of the product, not agreed upon by us, this declaration will lose its validity.

Factory : Zeilweg 44
60439 Frankfurt am Main / Germany

Telephone / Fax : +49 (0)69 8700257-20 / +49 (0)69 8700257-90

e-mail : info@rosenberg-group.de

Description of Product : NITRILE GLOVES

Trade Mark : ROSENBERG

Type Of Product : PPE

Applicable Directives : (EU) 2016/425 Personal Protective Equipment Directive

Applicable Harmonized Standards : EN ISO 374-1:2016, EN 374-2:2014, EN 374-3:2015, EN 374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015, EN 420:2003+A1:2009, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ASTM D6319 - 19

Title of Signatory : Bora F. Akcal

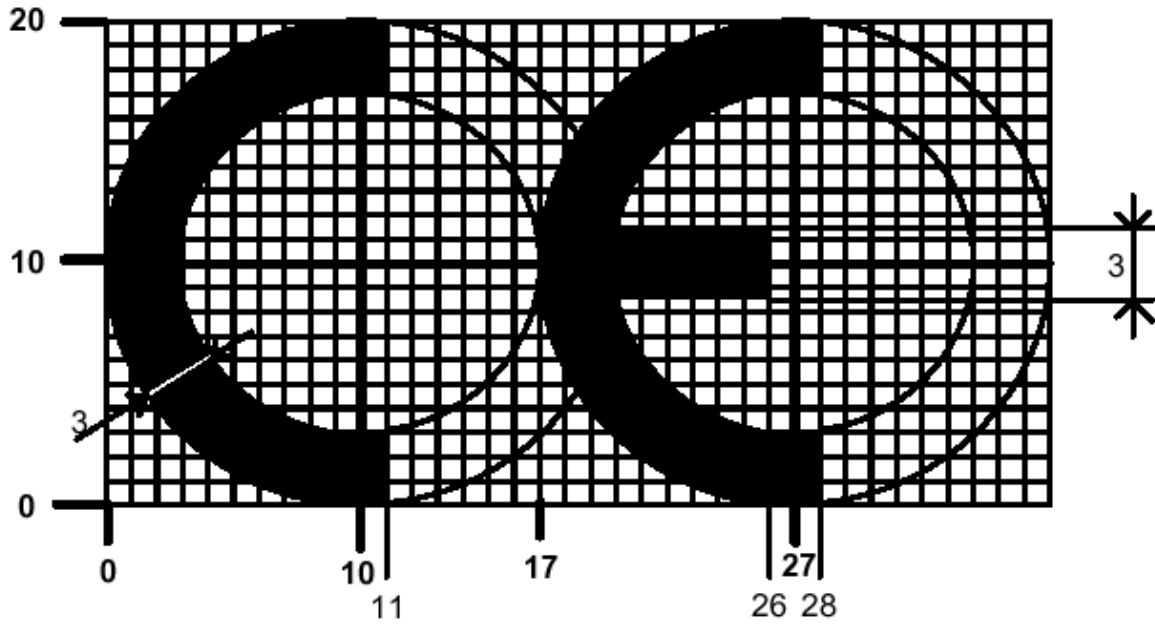
Company Stamp/Authorized Signature:

Date of registration : 26.02.2021

Date of expiry: : 3 YEARS



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- The CE mark will be enlarged or reduced, and the angle is appropriate to the ratios given in the graph.
- The letters of the CE mark appear in the game style and vertical dimensions. Navy blue should be less than 5 millimeters.

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STANDARDS USED IN PRODUCTION

EN ISO 374-1:2016
EN 374-2:2014
EN 374-3:2015
EN 374-4:2013
EN ISO 374-5:2016
EN 16523-1:2015
EN 420:2003+A1:2009
EN 455-1:2020
EN 455-2:2015
EN 455-3:2015
EN 455-4:2009
ASTM D6319 - 19

The harmonized standards used in production are stored in the STANDARDS file.



Registration Certificate

ZERTIFIKAT · 证书 · CERTIFICADO · CERTIFICAT · SERTIFIKA
ATTESTATIONS OF CONFORMITY

certifies that the company

ROSENBERG GMBH

Zeilweg 44

60439 Frankfurt am Main / Germany

has been verified and recognized as
manufacturer of

NITRIL ELDIVEN

NITRILE GLOVES

according to the rules of
(EU) 2016/425 PERSONAL PROTECTIVE DIRECTIVE

EN ISO 374-1:2016, EN 374-2:2014, EN 374-3:2015, EN 374-4:2013,
EN ISO 374-5:2016, EN 16523-1:2015, EN 420:2003+A1:2009,
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009,
ASTM D6319 - 19

Certificate-no:01043

CE marking can be affixed on the product after the preparation of the necessary technical documentation and the conformity declaration as well as the production control guaranteed by the manufacturer and the provision of the other directive fulfilled if any

First Registration Date: 26.02.2021
Certificate Date: 26.02.2021

Expiry Date: 26.02.2022
Period of Registration: 3 years

CE



Executive Manager



Certificate of Registration

This is to certify that
**Occupational Health and
Safety Management System**

of

ROSENBERG GMBH

Zeilweg 44 - 60439 Frankfurt am Main / Germany

complies with requirements of

ISO 45001:2018

This certificate is valid concerning all activities related to:

1-PLY DISPOSABLE SURGICAL FACE MASK, 2-PLY DISPOSABLE SURGICAL FACE MASK, 3-PLY DISPOSABLE SURGICAL FACE MASK, N95 TYPE MASK, FFP1 TYPE MASK, FFP2 TYPE MASK, FFP3 TYPE MASK, PROTECTIVE COVERALL, ISOLATION/SURGICAL GOWNS, DISPOSABLE SHOE COVER, DISPOSABLE SURGICAL COVERS, DISPOSABLE EXAMINATION COVERS, DISPOSABLE SURGICAL CAP, DISPOSABLE LATEX GLOVES, DISPOSABLE NITRILE GLOVES, DISPOSABLE VINYL GLOVES, DISPOSABLE STRETCHER COVER, BODY BAG, WOVEN WOMEN OUTERWEAR AND DIGITAL PRINTING TEXTILE PRODUCTS

TEK KULLANIMLIK TEK KATLI CERRAHI MASKE, TEK KULLANIMLIK İKİ KATLI CERRAHI MASKE, TEK KULLANIMLIK ÜÇ KATLI CERRAHI MASKE, N95 TIP MASKE, FFP1, FFP2 VE FFP3 TIP MASKE, TEK KULLANIMLIK KORUYUCU TULUM, TEK KULLANIMLIK CERRAHI ÖNLÜK, TEK KULLANIMLIK CERRAHI ÖRTÜ, TEK KULLANIMLIK MUAYENE ÖRTÜLERİ, TEK KULLANIMLIK BÖNE, TEK KULLANIMLIK GALOŞ, TEK KULLANIMLIK LATEKS ELDİVEN, TEK KULLANIMLIK NİTRİL ELDİVEN, TEK KULLANIMLIK VINİL ELDİVEN, TEK KULLANIMLIK SEDYE ÖRTÜSÜ, CESET TORBASI İLE DOKUMA BAYAN DIŞ GIYIM VE DİJİTAL BASKI TEKSTİL ÜRÜNLERİ ÜRETİMİ

ISO 11128 1360

Certificate No.

Mar. 2, 2021

Date of this Certificate

Mar. 1, 2022

Certification Expiry Date

Feb. 24, 2021

Date of Audit

Mar. 2, 2021

Date of Registration


Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
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* In Case if Surveillance Audit is not allowed to be conducted on or before the specified date, the Certificate shall be Suspended/Withdrawn





Certificate of Registration

This is to certify that
Environmental Management System

of

ROSENBERG GMBH

Zellweg 44 - 60439 Frankfurt am Main / Germany

complies with requirements of

ISO 14001:2015

This certificate is valid concerning all activities related to:

1-PLY DISPOSABLE SURGICAL FACE MASK, 2-PLY DISPOSABLE SURGICAL FACE MASK, 3-PLY DISPOSABLE SURGICAL FACE MASK, N95 TYPE MASK, FFP1 TYPE MASK, FFP2 TYPE MASK, FFP3 TYPE MASK, PROTECTIVE COVERALL, ISOLATION/SURGICAL GOWNS, DISPOSABLE SHOE COVER, DISPOSABLE SURGICAL COVERS, DISPOSABLE EXAMINATION COVERS, DISPOSABLE SURGICAL CAP, DISPOSABLE LATEX GLOVES, DISPOSABLE NITRILE GLOVES, DISPOSABLE VINYL GLOVES, DISPOSABLE STRETCHER COVER, BODY BAG, WOVEN WOMEN OUTERWEAR AND DIGITAL PRINTING TEXTILE PRODUCTS

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ISO 03 1127 1360

Certificate No.

Feb. 23, 2021

Date of Audit

Mar. 2, 2021

Date of this Certificate

Mar. 2, 2021

Date of Registration

Mar. 1, 2022

Certification Expiry Date

Managing Director / Director



Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
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Certificate of Registration

This is to certify that

**Quality Management System
for Medical Devices**

of

ROSENBERG GMBH

Zeilweg 44 - 60439 Frankfurt am Main / Germany

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to:

1-PLY DISPOSABLE SURGICAL FACE MASK, 2-PLY DISPOSABLE SURGICAL FACE MASK, 3-PLY DISPOSABLE SURGICAL FACE MASK, N95 TYPE MASK, FFP1 TYPE MASK, FFP2 TYPE MASK, FFP3 TYPE MASK, PROTECTIVE COVERALL, ISOLATION/SURGICAL GOWNS, DISPOSABLE SHOE COVER, DISPOSABLE SURGICAL COVERS, DISPOSABLE EXAMINATION COVERS, DISPOSABLE SURGICAL CAP, DISPOSABLE LATEX GLOVES, DISPOSABLE NITRILE GLOVES, DISPOSABLE VINYL GLOVES, DISPOSABLE STRETCHER COVER, BODY BAG, WOVEN WOMEN OUTHWEAR AND DIGITAL PRINTING TEXTILE PRODUCTS

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ISO 02 1129 1360

Certificate No.

Feb. 25, 2021

Date of Audit

Mar. 2, 2021

Date of this Certificate

Mar. 2, 2021

Date of Registration

Mar. 1, 2022

Certification Expiry Date

Managing Director / Director



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Certificate of Registration

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of
ROSENBERG GMBH

Zeilweg 44 - 60439, Frankfurt am Main / Germany

complies with requirements of

ISO 9001:2015

This certificate is valid concerning all activities related to:

1-PLY DISPOSABLE SURGICAL FACE MASK, 2-PLY DISPOSABLE SURGICAL FACE MASK, 3-PLY DISPOSABLE SURGICAL FACE MASK, N95 TYPE MASK, FFP1 TYPE MASK, FFP2 TYPE MASK, FFP3 TYPE MASK, PROTECTIVE COVERALL, ISOLATION/SURGICAL GOWNS, DISPOSABLE SHOE COVER, DISPOSABLE SURGICAL COVERS, DISPOSABLE EXAMINATION COVERS, DISPOSABLE SURGICAL CAP, DISPOSABLE LATEX GLOVES, DISPOSABLE NITRILE GLOVES, DISPOSABLE VINYL GLOVES, DISPOSABLE STRETCHER COVER, BODY BAG, WOVEN WOMEN OUTERWEAR AND DIGITAL PRINTING TEXTILE PRODUCTS

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ISO 01-1126-1360

Certificate No.

Mar. 2, 2021

Date of this Certificate

Mar. 1, 2022

Certification Expiry Date

Feb. 22, 2021

Date of Audit

Mar. 2, 2021

Date of Registration

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ROSENBERG[®]



2020

CERTIFICATE OF REGISTRATION

This certifies that

[Redacted]

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: [Redacted]
Device Classification Name:

**POLYMER PATIENT EXAMINATION
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23666, USA
Telephone: +1-757-224-0177
224-0179**

Product Code:
Regulation Number:
Official Correspondent
and U.S. Agent:

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 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 Lenhart
Executive Director
Registrar Corp
Dated: July 20, 2020



2020

CERTIFICATE OF REGISTRATION

This certifies that

[Redacted]

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: [Redacted]
Device Classification Name:

**LATEX PATIENT EXAMINATION
GLOVE
LYY
880.6250
Registrar Corp
144 Research Drive, Hampton, Virginia,
23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-
224-0179**

Product Code:
Regulation Number:
Official Correspondent
and U.S. Agent:

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.

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Registrar Corp

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David Lenhart
Executive Director
Registrar Corp
Dated: July 20, 2020

For more information please contact:

Rosenberg GmbH

Zeilweg 44 | 60439 Frankfurt

Tel: 069-870025720 | Fax: 069-870025790

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ROSENBERG®

Brand



Rosenberg Disposable Examination Nitril Gloves

100 pcs. per Box

FOB : US \$
CIF SEA : US \$
CIP AIR: US \$

Price will be regulated every 3 month

CIF SEA delivery 25-41 working days
CIP AIR delivery 10-15 working days

PAYMENT TERMS ONLY:

100% SBLC or ESCROW at Top Ten Bank



FDA ; CE ; ISO 9001:2015 ; ISO 14001:2015 ; ISO 13485 :2016 ; ISO 45001:2018 ; FDA-510K ; ATM D3578 ;
ASTM D6319-19 ; EN455-1,2,3,4 ; EN374-1,2,3,4,5 ; EN420:2003+A1:2009 ; EN16523-1:2015

Rosenberg Disposable Examination Nitril Gloves „Comfort“

200 pcs. per Box

FOB : US\$
CIF SEA : US\$
CIP AIR: US\$

Price will be regulated every 3 month

CIF SEA delivery 25-41 working days
CIP AIR delivery 10-15 working days

PAYMENT TERMS ONLY:

100% SBLC or ESCROW at Top Ten Bank



FDA ; CE ; ISO 9001:2015 ; ISO 14001:2015 ; ISO 13485 :2016 ; ISO 45001:2018 ; FDA-510K ; ATM D3578 ;
ASTM D6319-19 ; EN455-1,2,3,4 ; EN374-1,2,3,4,5 ; EN420:2003+A1:2009 ; EN16523-1:2015

Rosenberg Disposable Examination Nitril Gloves „Economy“

300 pcs. per Box

FOB : US\$
CIF SEA : US\$
CIP AIR: US\$

Price will be regulated every 3 month

CIF SEA delivery 25-41 working days
CIP AIR delivery 10-15 working days

PAYMENT TERMS ONLY:

100% SBLC or ESCROW at Top Ten Bank



FDA ; CE ; ISO 9001:2015 ; ISO 14001:2015 ; ISO 13485 :2016 ; ISO 45001:2018 ; FDA-510K ; ATM D3578 ;
ASTM D6319-19 ; EN455-1,2,3,4 ; EN374-1,2,3,4,5 ; EN420:2003+A1:2009 ; EN16523-1:2015



ROSENBERG[©]

For more information please contact:

Rosenberg GmbH

Zeilweg 44 | 60439 Frankfurt am Main

Tel: +49 69 870025720 | Fax: +49 69 870027590

E-Mail: info@rosenberg-group.de

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ROSENBERG GMBH

Zeilweg 44 | 60439 Frankfurt am Main – GERMANY

Tel: +49 69 8700257-20 | Fax: -90 | E-Mail: info@rosenberg-group.de | www.rosenberg-group.de

FRANKFURT | MANNHEIM | LONDON | MILAN | ISTANBUL | NEW YORK

Protects against dangerous chemicals and microorganisms

These gloves are made from nitrile (Acrylonitrile), and are designed to provide an excellent biological barrier and good resistance to bacteria. They are also resistant to a wide range of chemicals. However, they are not resistant to all chemicals. Some chemicals, such as strong acids and bases, can degrade the nitrile material. Therefore, it is recommended to check the chemical compatibility chart for the nitrile gloves you are using. The nitrile gloves are designed to provide an excellent biological barrier and good resistance to bacteria. They are also resistant to a wide range of chemicals. However, they are not resistant to all chemicals. Some chemicals, such as strong acids and bases, can degrade the nitrile material. Therefore, it is recommended to check the chemical compatibility chart for the nitrile gloves you are using.

Factor to consider in selection of chemical resistant gloves:

When used properly, nitrile gloves provide excellent resistance to a wide range of chemicals. However, they are not resistant to all chemicals. Some chemicals, such as strong acids and bases, can degrade the nitrile material. Therefore, it is recommended to check the chemical compatibility chart for the nitrile gloves you are using.

Thickness: 5 mil

Cuff Thickness: 5.0mm

Finger Thickness: 0.15mm

Palm Thickness: 0.15mm

ISO 13485

EN 374-3:2016

EN 374-2:2016

EN 374-1:2016

EN 374-4:2016

EN 374-5:2016

EN 374-6:2016

EN 374-7:2016

EN 374-8:2016

EN 374-9:2016

EN 374-10:2016

EN 374-11:2016

EN 374-12:2016

EN 374-13:2016

EN 374-14:2016

EN 374-15:2016

EN 374-16:2016

EN 374-17:2016

EN 374-18:2016

EN 374-19:2016

EN 374-20:2016

EN 374-21:2016

EN 374-22:2016

EN 374-23:2016

EN 374-24:2016

EN 374-25:2016

EN 374-26:2016

EN 374-27:2016

EN 374-28:2016

EN 374-29:2016

EN 374-30:2016

EN 374-31:2016

EN 374-32:2016

EN 374-33:2016

EN 374-34:2016

EN 374-35:2016

EN 374-36:2016

EN 374-37:2016

EN 374-38:2016

EN 374-39:2016

EN 374-40:2016

EN 374-41:2016

EN 374-42:2016

EN 374-43:2016

EN 374-44:2016

EN 374-45:2016

EN 374-46:2016

EN 374-47:2016

EN 374-48:2016

EN 374-49:2016

EN 374-50:2016

EN 374-51:2016

EN 374-52:2016

EN 374-53:2016

EN 374-54:2016

EN 374-55:2016

EN 374-56:2016

EN 374-57:2016

EN 374-58:2016

EN 374-59:2016

EN 374-60:2016

EN 374-61:2016

EN 374-62:2016

EN 374-63:2016

EN 374-64:2016

EN 374-65:2016

EN 374-66:2016

EN 374-67:2016

EN 374-68:2016

EN 374-69:2016

EN 374-70:2016

EN 374-71:2016

EN 374-72:2016

EN 374-73:2016

EN 374-74:2016

EN 374-75:2016

EN 374-76:2016

EN 374-77:2016

EN 374-78:2016

EN 374-79:2016

EN 374-80:2016

EN 374-81:2016

EN 374-82:2016

EN 374-83:2016

EN 374-84:2016

EN 374-85:2016

EN 374-86:2016

EN 374-87:2016

EN 374-88:2016

EN 374-89:2016

EN 374-90:2016

EN 374-91:2016

EN 374-92:2016

EN 374-93:2016

EN 374-94:2016

EN 374-95:2016

EN 374-96:2016

EN 374-97:2016

EN 374-98:2016

EN 374-99:2016

EN 374-100:2016

ROSENBERG®

Disposable Examination Gloves



Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

100 Pieces by weight

XL L M S

CE

FDA

ASTM

PPE

MDD

POWDER

LATEX

Schutz vor gefährlichen Chemikalien und Mikroorganismen

Diese Handschuhe bestehen zu 100% aus Nitril (Acrylonitril) und bieten eine hervorragende biologische Barriere und eine gute Resistenz gegen Bakterien, Pilze, Viren und eine Vielzahl von Chemikalien, die in typischen medizinischen und industriellen Umgebungen vorkommen. Es wird empfohlen zu überprüfen, ob die Handschuhe für den vorgesehenen Verwendungszweck geeignet sind, da die Bedingungen am Arbeitsplatz je nach Temperatur, Abrieb und Verschlechterung von der Typenprüfung abweichen können. Bei Verwendung können Schutzhandschuhe aufgrund von Änderungen der physikalischen Eigenschaften eine geringere Beständigkeit gegenüber der gefährlichen Chemikalie bieten. Bewegungen, Verhaken, Reiben, Verschlechterung durch chemischen Kontakt usw. können die tatsächliche Verwendungsdauer erheblich verkürzen. Bei toxischen Chemikalien kann der Abbau der wichtigste Faktor bei der Auswahl chemikalienbeständiger Handschuhe sein.

Textured Fingertips

EN 374-3:2016

5 Mil Thickness

Nitrile Blue

100 Pieces by weight

XL L M S

CE

FDA

ASTM

PPE

MDD

POWDER

LATEX



ROSENBERG®

Disposable Examination Gloves

MD LOT RB123456 2021-02-01 2025-02-01

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

100 Pieces by weight

XL L M S

CE

FDA

ASTM

PPE

MDD

POWDER

LATEX



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 Rosenberg Disposable Nitrile Examination Gloves
 ROSENBERG GmbH
 GmbH | 41060 Rosenberg | Germany
 Email: info@rosenberg-gloves.de
 Web: www.rosenberg-gloves.de

Protects against dangerous chemicals and microorganisms

These gloves are made from nitrile (Acrylonitrile), and are designed to provide an excellent biological barrier and good resistance to abrasion. Nitrile gloves are made to provide a superior chemical barrier to most common laboratory and industrial chemicals. They are designed to provide a superior barrier to most common laboratory and industrial chemicals. They are designed to provide a superior barrier to most common laboratory and industrial chemicals.

When used properly, nitrile gloves provide excellent resistance to the majority of common laboratory and industrial chemicals. However, nitrile gloves are not resistant to all chemicals. Degradation can be the most important factor to consider in selection of chemical resistant gloves.

For more information on nitrile gloves, please visit our website at www.rosenberg.com.

Hand Length: 240 mm (9.45 in)

Thickness	5 mil
Finger Thickness	5.0 mm
Cuff Thickness	0.1 mm

ISO 15184
EN 374-3:2016
EN 374-2:2016
EN 374-1:2016
EN 374-4:2016
EN 374-5:2016
EN 374-6:2016
EN 374-7:2016
EN 374-8:2016
EN 374-9:2016
EN 374-10:2016
EN 374-11:2016
EN 374-12:2016
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EN 374-86:2016
EN 374-87:2016
EN 374-88:2016
EN 374-89:2016
EN 374-90:2016
EN 374-91:2016
EN 374-92:2016
EN 374-93:2016
EN 374-94:2016
EN 374-95:2016
EN 374-96:2016
EN 374-97:2016
EN 374-98:2016
EN 374-99:2016
EN 374-100:2016

ROSENBERG®

Disposable Examination Gloves

Comfort

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

200 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE, LATEX, POWDER

Schutz vor gefährlichen Chemikalien und Mikroorganismen

Diese Handschuhe bestehen zu 100% aus Nitril (Acrylonitril) und bieten eine hervorragende biologische Barriere und eine gute Resistenz gegen Bakterien, Pilze, Viren und eine Vielzahl von Chemikalien, die in typischen medizinischen und industriellen Umgebungen vorkommen. Es wird empfohlen zu überprüfen, ob die Handschuhe für den vorgesehenen Verwendungszweck geeignet sind, da die Bedingungen am Arbeitsplatz je nach Temperatur, Abrieb und Verschlechterung von der Typenprüfung abweichen können. Bei Verwendung können Schutzhandschuhe aufgrund von Änderungen der physikalischen Eigenschaften eine geringere Beständigkeit gegenüber der gefährlichen Chemikalie bieten. Bewegungen, Verhaken, Reiben, Verschlechterung durch chemischen Kontakt usw. können die tatsächliche Verwendungsdauer erheblich verkürzen. Bei ätzenden Chemikalien kann der Abbau der wichtigste Faktor bei der Auswahl chemikalienbeständiger Handschuhe sein.

Textured Fingertips

EN 374-3:2016

5 Mil Thickness

Nitrile Blue

200 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE, LATEX, POWDER



ROSENBERG®

Disposable Examination Gloves

MD LOT RB123456 2021-02-01 2025-02-01

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

200 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE, LATEX, POWDER



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Rosenberg Disposable Nitrile Examination Gloves Manufactured by:
ROSENBERG GmbH
Email: info@rosenberg.com
Web: www.rosenberg.com

Protects against dangerous chemicals and microorganisms

These gloves are made from nitrile (Acrylonitrile), and are designed to provide an excellent biological barrier and good resistance to abrasion. Nitrile gloves are made of synthetic chemical compounds and do not contain any natural latex proteins. They are therefore safe for people with latex allergies. It is recommended to check that the gloves are suitable for the intended use because the nitrile gloves offer resistance to the majority of dangerous chemicals and are not permeable to the majority of dangerous chemicals. However, chemical degradation can be the most important factor to consider in selection of chemical resistant gloves.

For more information please refer to the technical data sheet for the gloves. For more information please refer to the technical data sheet for the gloves.

240 mm length

5 mil Thickness

5.0mm Finger Thickness
5.0mm Palm Thickness
0.15mm Wristband

ISO 13485
EN 374-5:2016
EN 374-3:2016
EN 374-4:2016
EN 374-2:2016
EN 374-1:2016
EN 374-6:2016
EN 374-7:2016
EN 374-8:2016
EN 374-9:2016
EN 374-10:2016
EN 374-11:2016
EN 374-12:2016
EN 374-13:2016
EN 374-14:2016
EN 374-15:2016
EN 374-16:2016
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EN 374-36:2016
EN 374-37:2016
EN 374-38:2016
EN 374-39:2016
EN 374-40:2016
EN 374-41:2016
EN 374-42:2016
EN 374-43:2016
EN 374-44:2016
EN 374-45:2016
EN 374-46:2016
EN 374-47:2016
EN 374-48:2016
EN 374-49:2016
EN 374-50:2016

ROSENBERG®

Disposable Examination Gloves

Economy

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

300 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE

Schutz vor gefährlichen Chemikalien und Mikroorganismen

Diese Handschuhe bestehen zu 100% aus Nitril (Acrylonitril) und bieten eine hervorragende biologische Barriere und eine gute Resistenz gegen Bakterien, Pilze, Viren und eine Vielzahl von Chemikalien, die in typischen medizinischen und industriellen Umgebungen vorkommen. Es wird empfohlen zu überprüfen, ob die Handschuhe für den vorgesehenen Verwendungszweck geeignet sind, da die Bedingungen am Arbeitsplatz je nach Temperatur, Abrieb und Verschlechterung von der Typenprüfung abweichen können. Bei Verwendung können Schutzhandschuhe aufgrund von Änderungen der physikalischen Eigenschaften eine geringere Beständigkeit gegenüber der gefährlichen Chemikalie bieten. Bewegungen, Verholken, Reißen, Verschlechterung durch chemischen Kontakt usw. können die tatsächliche Verwendungsdauer erheblich verkürzen. Bei toxischen Chemikalien kann der Abbau der wichtigste Faktor bei der Auswahl chemikalienbeständiger Handschuhe sein.

Textured Fingertips

EN 374-5:2016

5 Mil Thickness

Nitrile Blue

300 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE

ROSENBERG®

Disposable Examination Gloves

MD LOT RB123456 2021-02-01 2025-02-01

Powder-Free / Non-Sterile / Single-Use / Ambidextrous

Textured Fingertips

5 Mil Thickness

Nitrile Blue

300 Pieces by weight

XL L M S

CE, FDA, ASTM, PPE, MDD, NITRILE

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Rosenberg Disposable Nitrile Examination Gloves Manufactured by:
ROSENBERG GmbH
Email: info@rosenberg-gmbh.de
Web: www.rosenberg-gmbh.de

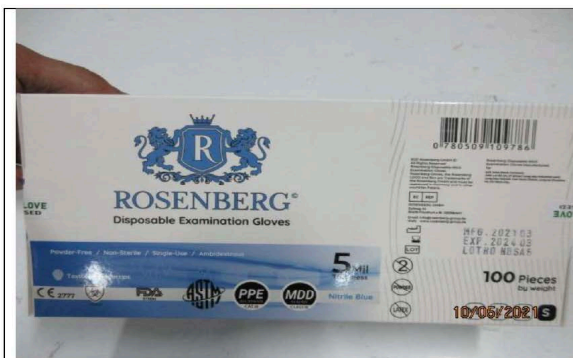
ROSENBERG®

Disposable Examination Gloves

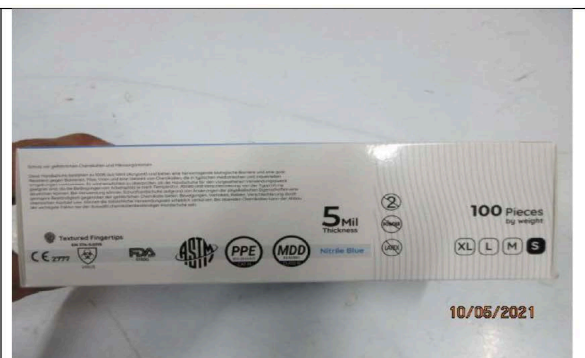
1 Palet = 100 Cartons

1 Carton = 10 Boxes

1 Box = 100 pcs. Nitrile Gloves



View of marking on inner box



View of marking on inner box



View of marking on inner box



View of marking on inner box

365 mm

230 mm

365 mm

230 mm

115 mm

236 mm

115 mm

ROSENBERG®
Disposable Examination Gloves

Rothenberg GmbH
Zeilweg 14
62483 Frankfurt a.M. / GERMANY
Medical Devices
Personal Protection
Equipment

M



10 Boxes

Energy: Hersteller
Hersteller
Hersteller

CE 2777



ROSENBERG®
Disposable Examination Gloves
Nitrile Blue



ROSENBERG GMBH & CO. JOINT STOCK COMPANY
Postfach 10000, D-62483 Frankfurt, Germany
Long Hai, Hainan, Can Gio District, Long An Province, Ho Chi Minh City.

10 Boxes

Energy: Hersteller
Hersteller
Hersteller

CE 2777



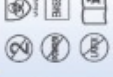
ROSENBERG®
Disposable Examination Gloves



10 Boxes

Energy: Hersteller
Hersteller
Hersteller

CE 2777



ROSENBERG®
Disposable Examination Gloves
Nitrile Blue



Preservation

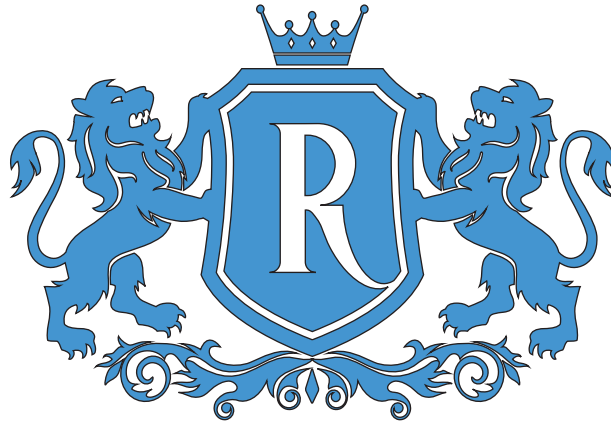
1. Store in a dry and dark space
2. Maximum storage temperature 30 degrees Celsius (86°F)
3. Gloves do not protect you from radiation
4. Do not use gloves with strong acidic or basic solutions

10 Boxes

Energy: Hersteller
Hersteller
Hersteller

CE 2777





ROSENBERG®



ROSENBERG GMBH

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Tel: +49 69 8700257-20 Fax: -90 | E-Mail: info@rosenberg-group.de | www.rosenberg-group.de

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