

# Gloves vinyl

## Technical data sheet



**ID name:** Medical Vinyl Gloves

**Intended use:**

To protect against infections. Disposable. Latex-free.

**Caution for use:**

None sterile. Avoid direct contact with the wound.

**CE Class:** I

**Product properties:**

Material: Vinyl

Color: Semi-transparent

Size: L ( Length:  $\geq$  230mm Width 109mm

Thickness:  $\geq$ 0.08mm and  $\leq$ 0.22mm

**Storage:**

Should be stored in a cool dry environment for best results of product performance. Keep away from light and heat.

**Shelf life:**

5 Years

**Legal manufacturer:**

RFX+CARE Manufacturing Co., Ltd. 7 Lanjiang Road, Yuecheng District, Shaoxing, Zhejiang, China 312000.

**EC-Representative:**

RFX+Care International A/S. Bakkegaardsvej 408, 3050 Humlebaek, Denmark

**Certificates TÜV SÜD:**

EN ISO 13485:2016

**Reference reports and certificates:**

Annex. 1 ISO13485:2016 Certificate

Annex. 2 EN 374-1/2/3/4

Annex. 3 EN455-1/2/3

Annex. 4 EN16523

Annex. 5 EN388

Annex. 6 EN420

Annex. 7 ASTM D5250-06

Annex. 6 Conforms to DIN 13164:2014

For further information please send your request to [info@rfx-care.com](mailto:info@rfx-care.com)

EC-Representative: RFX+Care International A/S • Bakkegaardsvej 408 • 3050 Humlebaek • Denmark

# Gloves nitrile

## Technical data sheet



**ID name:** Nitrile gloves Medical gloves

**Intended use:**

To protect against infections. Disposable. Latex-free.

**Caution for use:**

None sterile. Avoid direct contact with the wound.

**CE Class:** I non sterile / PPE

**Product properties:**

Material: Nitrile without powder, NBR, Pigment

Color: Blue

Size: Large Length:  $\geq$  230mm Width 110mm

Thickness:  $\geq$ 0.08mm and  $\leq$ 0.22mm

**Storage:**

Should be stored in a cool dry environment for best results of product performance. Keep away from light and heat.

**Shelf life:**

5 Years Intended:

**Legal manufacturer:**

RFX+CARE Manufacturing Co., Ltd. 7 Lanjiang Road, Yuecheng District, Shaoxing, Zhejiang, China 312000.

**EC-Representative:**

RFX+Care International A/S. Bakkegaardsvej 408, 3050 Humlebaek, Denmark

**Certificates TÜV SÜD:**

EN ISO 13485:2016

**Reference reports and certificates:**

Annex.1 ISO 13485:2016 Certificate

Annex.2 EN 374-1/2/3

Annex.3 EN455-1/2/3

Annex.4 EN16523

Annex.5 EN388

Annex.6 EN420

Annex.7 ASTM D7329-07

Annex.8 FDA 21CFR177.2600

Annex.9 (EU) No 10/2011

For further information please send your request to [info@rfx-care.com](mailto:info@rfx-care.com)

EC-Representative: RFX+Care International A/S • Bakkegaardsvej 408 • 3050 Humlebaek • Denmark



Product Service

# Certificate

No. Q5 067759 0027 Rev. 01

**Holder of Certificate:** **RFX+CARE Manufacturing Co., Ltd.**

7 Lanjiang Road  
Yuecheng District  
312000 Shaoxing, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design, Development,  
Production and Distribution of  
First Aid Kits, Plasters, Condoms, Safety Kits and  
Silicone Foam Dressing

Production and Distribution of  
Bandage, Gauze Swabs, Non woven Swabs,  
Gauze Balls, Non woven Balls, Cotton Rolls,  
Shoe Covers, Face Masks, Emergency Blankets,  
Sterile Burn Dressing, Sterile Wound Dressing,  
Relieve Burn Gels, Alcohol Prep Pads,  
Sterile Single Use Wound Cleansing Swabs,  
Adhesive Strips/Tapes, Examination Gloves,  
Sterile Hydrocolloid Dressings,  
Sterile Single Use Cleaning Tubes,  
Thermometer, Warmers, Cold Packs, Hot Packs,  
Cold /Hot Pack, Sterile Eye Pads, Tweezers,  
Bandage Scissors, Respiratory Sheet, Wash Swabs,  
Blister Plasters, Sterile Non Woven Compress,  
Cleansing Swab and Tube, Alcohol Swabs,  
Instant Cold Packs, Wound Skin Closure Strips,  
Sterile Absorbent Pad, Bee Plasters, Sterile Cotton Balls,  
Tick Removers, Forehead Thermometers, Eye Wash,  
Sickness Bands, Sports Supports and Foot Care Cushion

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1952701

**Valid from:** 2020-01-29

**Valid until:** 2022-10-31

**Date,** 2020-01-29

Christoph Dicks  
Head of Certification/Notified Body

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**ZERTIFIKAT** ◆ **CERTIFICATE** ◆ 認證證書 ◆ **CЕРТИФИКАТ** ◆ **CERTIFICADO** ◆ **CERTIFICAT**



Product Service

# Certificate

**No. Q5 067759 0027 Rev. 01**

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):** RFX+CARE Manufacturing Co., Ltd.  
 7 Lanjiang Road, Yuecheng District, 312000 Shaoxing, Zhejiang,  
 PEOPLE'S REPUBLIC OF CHINA

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