**RFB GLOVES**
SDF No. C-08(C) and Plot No. 129G/53,
Noida Special Economic Zone, Noida -
201305, UP, India

# RADIATION PROTECTION GLOVES
# RFB RX

## INSTRUCTIONS FOR USE

**INTENDED USE:**
To protect the user's hands from scattered secondary radiation originating from the X-ray beam during fluoroscopic procedures by providing an attenuating barrier to radiation. They are not intended for use in direct or primary X-ray beams.
These gloves are ideal where the user needs excellent dexterity together with a limited level of resistance to ionizing radiations during various types of procedures such as General X-Ray & Fluoroscopy, Radiography, Neuroradiology, Urology, MRI, CT, Radiotherapy and Nuclear Medicine.

**CAUTION AND WARNINGS**:
The glove complies with safety standards only if worn as recommended and only if in perfect condition. Glove is sterile and is single use only. The product is made from Dry Natural Rubber. Do not wear if packaging is damaged or has been tampered with.

**HAZARDS:**
Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction, seek medical assistance immediately.

These gloves are intended to protect against the risks caused by:
- Low level of ionizing radiation,
- Micro-organisms (fungi and bacteria, not virus)

They are not intended to protect in case of risks caused by:
- Abrasions, cuts, tears, punctures
- Heat and fire,
- All the uses not mentioned here

**PRECAUTIONS AND INDICATIONS FOR USE:**
Before use, visually check the glove pouch to make sure that the seal has not been tampered with. A tampered wrapping (visibly damaged with holes, cuts, tears, undone welding) must be discarded and replaced. The gloves too must be inspected before use: they must be in perfect condition, clean and intact and must be discarded and replaced if not perfectly intact (eg. visibly damaged - cut or torn) nor clean (eg. soiled). Aggressively pulling on the cuff and over stretching the glove while donning may lead to tearing or damage.

**EXPIRY DATE:**
The shelf life of a sterilized glove is 3 years. This Indication may be found on the label on the original external packaging and indicates the period during which the device, sterilized with Ethylene Oxide, may be used, provided it has been stored up until that moment with intact packaging and in suitable storage conditions.

**STORAGE AND MAINTENANCE INSTRUCTIONS:**
The glove must be stored in its original packaging, in a dry place away from light, heat and humidity. Store ideally at 10°C to 30°C and up to 60% relative humidity. Care should be taken to avoid sharp objects as through and through punctures will allow radiation to pass to the wearer.

**DISPOSAL:**
Used gloves might be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation.

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**COMPLIANCE STANDARDS:**

**EN 61331-1:2014:** (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material).

**ASTM 2547-18:** (USA) Standard test method for determining the attenuation properties in a primary x-ray beam of materials used against radiation.

**EN ISO 374-1:2016+A1:2018: S**pecifies the requirements for protective gloves intended to protect the user against dangerous chemicals and defines terms to be used.

**EN ISO 374-5:2016:** Protection against Bacteria and Fungi

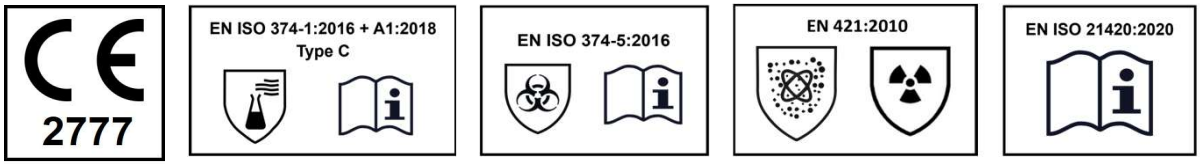
**EN ISO 21420:2020:** Defines general requirements valid for protective gloves and sets requirements for glove marketing.

**EN 421:2010:** Meets the requirements of EN421:2010 offering protection against ionizing radiation and radioactive contamination. Tested in accordance with ASTM F2547-18 and IEC 61331 and offers some attenuation of radiological risks.

| Type | Energy Level | | | |
|---|---|---|---|---|
| | 60 KVP | 80 KVP | 100 KVP | 120 KVP |
| RXL | 55% | 47% | 42% | 36% |
| RX1 | 62% | 53% | 47% | 43% |
| RX2 | 70% | 63% | 56% | 49% |
| The values may vary by ± 5%. Results refer to testing carried out in the palm area of the gloves. | | | | |

| Chemical Abbreviation | Chemical Name | Mean Degradation (%) EN ISO 374-4:2019 | Performance Level |
|---|---|---|---|
| K | 40% Sodium Hydroxide | -6.6 | Level 6 |
| L | 96% Sulphuric Acid | 66.7 | Level 3 |
| A | Methanol | -19.6 | N/A |

| Permeation levels are based on breakthrough times as follows: | | | | | | |
|---|---|---|---|---|---|---|
| Performance Level | 1 | 2 | 3 | 4 | 5 | 6 |
| Minimum Breakthrough times (mins) | >10 | >30 | >60 | >120 | >240 | >480 |




**EU DECLARATION OF CONFORMITY:**

This is to certify that the product Group Reference "RFB RX" and product variants "RFB XL/RXL", "RFB X1/ RX1", "RFB X2/ RX2" is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 and EN 421:2010 and is identical to the PPE which is subject to the EC type Examination certificate number 2777/20598-02/E00-00 issued by the Notified Body: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland (Notified Body: 2777). and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of SATRA Technology Europe Limited (Notified Body No. 2777).