

# EU Type Examination Certificate

This is to certify that:

WRP Asia Pacific Sdn Bhd  
Lot 1, Jalan 3  
Kawasan Perusahaan  
Bandar Baru Salak Tinggi  
Sepang  
Selangor  
43900  
Malaysia

Holds Certificate Number:

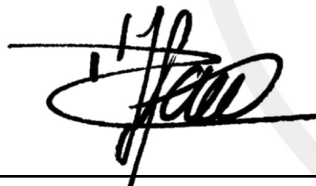
CE 724079

In respect of:

## **Polyisoprene Radiation Attenuation gloves**

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified  
Body for the above Regulation  
(Notified Body Number 2797):



Drs. Dave Hagenaaers, Managing Director

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# EU Type Examination Certificate

No. CE 724079

## Product Specification

**Model - Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile  
Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile**

**Classification:** Protective glove for use against chemical and micro-organism hazards and radiation.

**Description:** Powder Free PI Protective Gloves manufactured from polyisoprene.  
Inner surface of gloves is smooth surface that assists in donning the gloves without using lubricant such as powder on the glove surface.

The main features of this protective glove are:

- Beaded cuff
- Micro-organisms penetration resistance
- Chemical permeation resistance
- Palm and finger micro-textured (Hand Specific)

<b>Models in range:</b>	Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile						
	R3560-85	R3565-85	R3570-85	R3575-85	R3580-85	R3585-85	R3590-85
<b>Sizes</b>	Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile						
	R3560-86	R3565-86	R3570-86	R3575-86	R3580-86	R3585-86	R3590-86
	6.0	6.5	7.0	7.5	8.0	8.5	9.0

**Category:** Category III – complex

<b>Applicable Standards:</b>	EN ISO 21420:2020	General requirements for gloves
	EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination.
	EN ISO 374-1:2016+A1:2018	Protective gloves against chemicals & micro-organisms
	EN ISO 374-2:2019	Resistance to penetration
	EN ISO 374-4:2019	Resistance to degradation by chemicals
	EN ISO 374-5:2016	Resistance to penetration by blood borne tested
	EN 16523-1:2015+A1:2018	Determination of resistance to permeation by chemicals
	ISO 16604:2004	Resistance of clothing materials to penetration by blood-borne pathogens
EN 61331-3:2014	Protective devices against diagnostic medical X-radiation. Protective clothing, eyewear and protective patient shields	

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# EU Type Examination Certificate

No. CE 724079

## Product Specification (Continued)

**Model** – Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile

## Performance

**General requirements for gloves to EN ISO 21420:2020.**

**Characteristic Level**

Dexterity: 4

**Resistance to penetration to EN ISO 374-2:2019.**

Resistance to Water Leak Pass

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018/Type B  
(Test method EN 16523-1:2015+A1:2018)**

**Resistance to Degradation to chemical protection EN ISO 374-4:2019**

Chemical	Permeation Level	Mean Degradation %
40% Sodium hydroxide(K)	6	-32.5
30% Hydrogen peroxide (P)	5	-33.0
37% Formaldehyde (T)	6	-25.6

**Resistance to penetration by blood-borne tested to EN ISO 374-5:2016**

Protection against bacteria and fungi Pass

Protection against viruses Pass

**Protective gloves against radioactive contamination to EN 421:2010**

kV	Attenuation % Mean	LEV mm Pb Mean
60	63.02	0.034
80	53.67	0.035
100	48.53	0.035
120	43.11	0.036
150	-	0.036

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# EU Type Examination Certificate

No. CE 724079

## Product Specification (Continued)

**Model** – Radiaxon Polyisoprene Sensitive Powder Free Radiation Attenuating Surgical Gloves, Sterile

## Performance

**General requirements for gloves to EN ISO 21420:2020.**

### Characteristic Level

Dexterity: 5

**Resistance to penetration to EN ISO 374-2:2019.**

Resistance to Air & Water Leak Pass

**Resistance to chemical permeation to EN ISO 374-1:2016+A1:2018/Type B  
(Test method EN 16523-1:2015+A1:2018)**

**Resistance to Degradation to chemical protection EN ISO 374-4:2019**

Chemical	Permeation Level	Mean Degradation %
40% Sodium hydroxide(K)	6	-36.5
30% Hydrogen peroxide (P)	5	-36.5
37% Formaldehyde (T)	6	-3.1

**Resistance to penetration by blood-borne tested to EN ISO 374-5:2016**

Protection against bacteria and fungi Pass

Protection against viruses Pass

**Protective gloves against radioactive contamination to EN 421:2010**

kV	Attenuation % Mean	LEV mm Pb Mean
60	68.04	0.039
80	58.00	0.039
100	52.03	0.040
120	47.07	0.040
150	39.55	0.041

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## Certificate Administration Details

Technical File Reference: TF/PPE/009 – PI RPG

## Certificate Amendment Record

Issue date	Comments	BSI Internal report No.
December 2020	First issue.	2797:20:3145132

**Note:** The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), for the product are referenced in BSI issued Certificate number CE 688305

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