GENÇ

FDA

SURGICAL
ISOLATION GOWNS AND COVERALLS CATALOGUE

2020

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CE

ISO 9001:2015 | ISO 14001:2015 | ISO 113485:2016 | OHSAS 18001:2007

ISO 26000:2010 | ISO 22301:2014 | ISO 27001:2013

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GUIDE TO PROTECTIVE MATERIALS

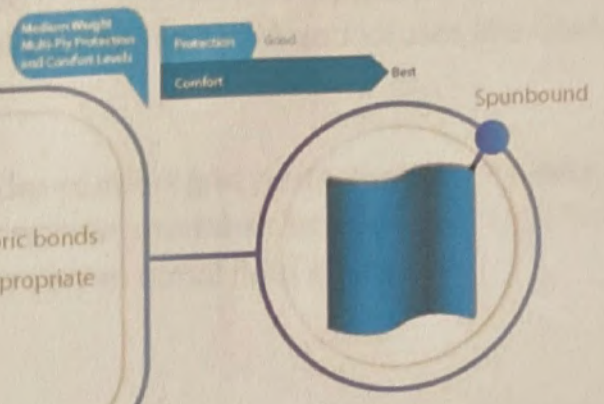
To help chose the right product, here is a brief description of the features and benefits of the main materials available at Genc Giyim;

Product Range and Materials Descriptions

GNC - 2207
Spunbond Polypropylene

Standard, cost-effective and comfortable

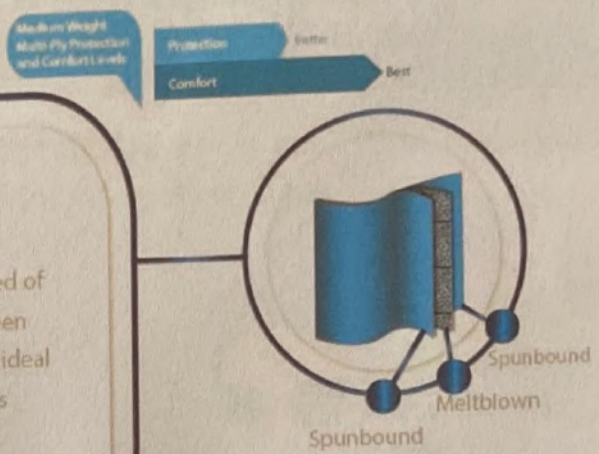
For basic infection control, this non-woven fabric bonds fibers together to form a single layer that is appropriate only for very minimal fluid exposure.



GNC - 2209
SMS Material

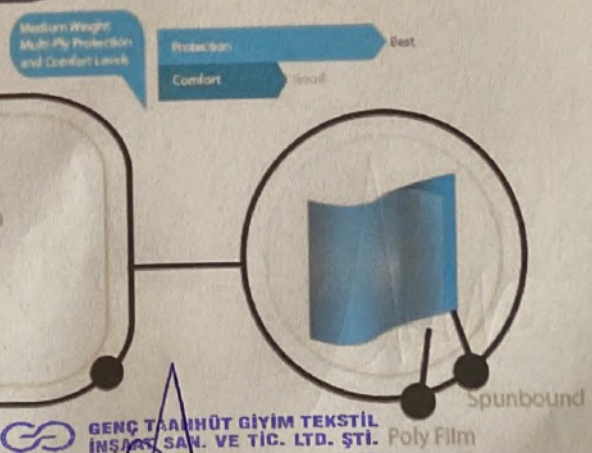
Balanced mix of protection and comfort

Strong and breathable, Spunbond/Meltblown/Spunbond (SMS) is a multi-layer fabric composed of inner layers of meltblown polypropylene between outer layers of spunbond polypropylene that is ideal for extended wear. Light/medium weight SMS is appropriate for low amounts of fluid and heavy weight SMS maybe appropriate for moderate contact with fluids.



GNC-2211
Coated Polypropylene ("Poly-coated")

Soft, spunbond polypropylene is coated with a layer of polyethylene (plastic) film.



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GNC - 2207 Isolation Gown - Light Weight PP

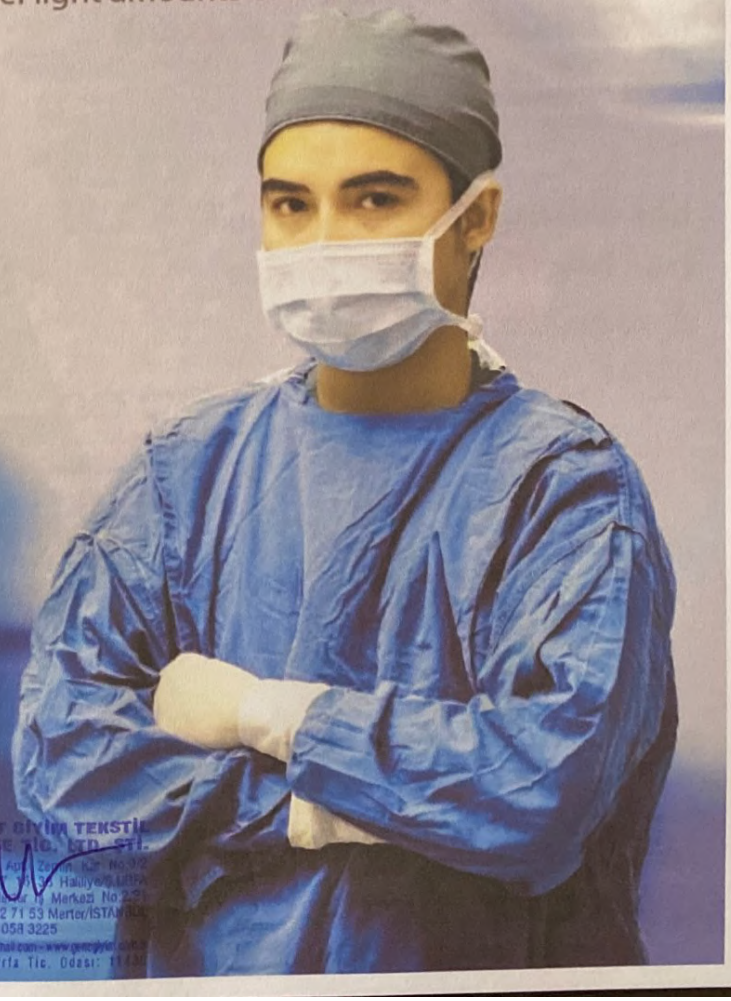
Personal Protective Equipment (PPE) is a two-way street. Originally developed to protect the healthcare worker, PPE when used properly can also represent the first line of defense against contact transfer of pathogens like MRSA and viruses like Covid-19.

Lightweight spunbond polypropylene provides comfort and protection in very minimal fluid settings. For basic infection control, this non-woven fabric bonds fibers together to form a single layer that is appropriate only for very minimal fluid exposure.

Our products provide high protection and great comfort.

Single layer spunbond isolation gown designed for dry particle protection, featuring full coverage. Also these gowns are able to repel light amounts of fluids.

- Meets AAMI Level 1 requirements
- Light PP fabric
- Natural rubber latex-free
- Low lint generation
- Anti-static treated fabric



Regulatory Compliance

Complience with
EN ISO 13485:2016,
EN 14971:2012 and
EN ISO 15223-1:2016

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GNC - 2207 Fluid Resistant, Isolation Gown Light Weight PP

GENÇ

Size
S to XL

Basic spunbond polypropylene gown Comfort and protection for use in very minimal fluid settings. Generously sized for greater coverage and flexibility.

Suitable for health care workers and visitors, helps to prevent contamination with particulates

Knit cuffs, ties at the neck and waist, breathable back

Full coverage, breathable and comfortable - Waist and neck ties, Elastic or Knit Cuffs

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GNC-2207

GNC ISOLATION GOWN

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GNC-2209 Isolation Gown- Medium Weight SMS

We know you rely on disposable apparel to keep your staff and patients protected and comfortable. For this reason, we use the finest materials available for protection, offering the greatest level of comfort. We apply the highest quality standards to our products and in our manufacturing facilities.

Using the latest advancements in SMS technology, GNC gowns offer outstanding softness and enhanced breathability. This light weight line has great moisture evaporation, leaving the wearer cool and dry. Those who spend much of the day in a surgical gown appreciate the comfort of GNC. Count on three fabric layers, meltblown layer sandwiched between two strong spunbound outer layers, for excellent barrier protection against fluids and pathogens.

Our products provides high protection and great comfort.

For use when expected risk of exposure to fluid is between low and moderate

- ✔ Meets AAMI Level 2 requirements
- ✔ Medium-weight SMS fabric
- ✔ Recommended for
- ✔ Su turing, blood draw, inserting I.V. lines, specimen handling, drawing arterial blood
- ✔ IC U, Med/Surg Unit, Hyperbaric and Dialysis Units, Labs and Pathology, Nursery

Regulatory Compliance

Complience with
EN 13795.,
EN ISO 13485:2016,
EN 14971:2012
and EN ISO 15223-1:2016

Latex-free protection

The "Latex-Free" symbol on all our gowns provides additional peace of mind for patients and clinicians.

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GNC-2209 Fluid Resistant, Isolation Gown Medium Weight SMS

GENÇ

Fluid Resistant, Isolation Gown - Medium Weight , SMS Suitable for procedures with moderate risks of exposure to nonbiological fluids.

Knit cuffs, ties at the neck and waist, breathable back

This Gown offers increased protection from non-biological fluids without sacrifiying the level of comfort and breathability.

- Class 6 for Resistance to wet bacterial penetration (EN ISO 22610 per EN 14126)
- Class 3 for Resistance to penetration by contaminated solid particles (EN ISO 22612 per EN 14126)
- Resistance to liquid penetration >200cmH2O

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GNC - 2209

GNC ISOLATION GOWN

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GNC - 2211 SURGICAL LAMINATED GOWN AGAINST LIQUIDS -PP + PE Microporous

We know you rely on disposable apparel to keep your staff and patients protected and comfortable. For this reason, we use the finest materials available for protection, offering the greatest level of comfort. We apply the highest quality standards to our products and in our manufacturing facilities.

GNC-2213 gown is a high performance gown. With microporous film technology, this surgical gown offers a superb combination of protection and comfort. Moisture vapor is 1,000 times smaller than the smallest viruses; hence 2211 gown blocks fluids while still allowing moisture vapour to escape, keeping the wearer dry and comfortable.

It provides great fluid protection. It is ideal for any situation demanding a high level of fluid protection. The Single Use Bilaminate Isolation Gowns are impervious and suitable for procedures with high risks of exposure to fluids.

- Meets AAMI Level 3 requirements
- High-weight PP fabric+PE Lamination
- Recommended for

Ideal for highly infectious situations and all operating room and ward applications. To prevent the spread of germs on emergency and isolation wards, in care homes, and in hospitals, for personnel, patients and visitors

Regulatory Compliance

Complience with
EN 13795.,
EN ISO 13485:2016,
EN 14971:2012
and EN ISO 15223-1:2016

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Latex-free protection

The "Latex-Free" symbol on all our gowns provides additional peace of mind for patients and clinicians.

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GNC - 2211 SURGICAL LAMINATED GOWN AGAINST LIQUIDS - PP + PE Microporous

GENÇ

Size
S to XL

Surgical Laminated Isolation Gown - PP + PE Microporous Suitable for procedures with high risks of exposure to fluids.

Knit cuffs, ties at the neck and waist, breathable back

- Class 6 for Resistance to wet bacterial penetration (EN ISO 22610 per EN 14126)
- Class 3 for Resistance to penetration by contaminated solid particles (EN ISO 22612 per EN 14126)
- Resistance to liquid penetration >500cmH2O

GNC-2211

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USA Levels of Barrier Protection Standards

AAMI(The Association for the Advancement of Medical Instrumentation) PB70 guidelines

GNC-2209 is classified by AAMI PB70 guidelines as PPE Level 2 Level 2 while GNC-2211 is classified as PPE Level 3 according to the Directive 89/686/EEC or MDD Class I non sterile according to the Directive 93/42/EEC.

ANSI/AAMI PB70 BARRIER PERFORMANCE	TEST METHOD	TEST DEFINITIO	REQUIREMENT	ANTICIPATED FLUID XPOSURE
AAMI Level 1	Water resistance: Impact penetration AATCC 42	AATCC42 Measures the resistance of fabrics to the liquid penetration of water by impact	Water impact < 4.5 g	Minimal fluid levels
AAMI Level 2	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure	Spray impact < 1.0 g Hydrostatic Pressure > 20 cm	Low fluid levels
AAMI Level 3	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure	Spray impact < 1.0 g Hydrostatic Pressure > 50 cm	Moderate fluid levels
AAMI Level 4	ASTM F1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System	ASTM F1671 Measures the resistance of materials used in protective clothing to penetration by blood borne pathogens using a surrogate microbe under conditions of continuous liquid contact.	Pass	High fluid levels

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Association for the Advancement of Medical Instrumentation. Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities. ANSI/AAMI PB70:2012. Arlington, VA: AAMI.

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EU PERFORMANCE REQUIREMENTS AND PERFORMANCE LEVELS FOR SURGICAL GOWNS EN 13795

GNC-2209 AND GNC-2211 COMPLY WITH PERFORMANCE REQUIREMENTS FOR SURGICAL GOWNS BELOW;

PERFORMANCE REQUIREMENTS FOR SURGICAL GOWNS

CHARACTERISTIC	UNIT	STANDARD PERFORMANCE		HIGH PERFORMANCE	
		CRITICAL AREA	LESS CRITICAL AREA	CRITICAL AREA	LESS CRITICAL AREA
RESISTANCE TO MICROBIAL PENETRATION – DRY	LOG_{10} (CFU)	N/A	≤2[a,c]	N/A	≤2[a,c]
RESISTANCE TO MICROBIAL PENETRATION – WET	BI	≥2,8[b]	N/A	6,0[b,d]	N/A
CLEANLINESS – MICROBIAL	LOG_{10} (CFU/dm²)	≤2[c]	≤2[c]	≤2[c]	≤2[c]
CLEANLINESS – PARTICULATE MATTER	IPM	≤3,5	≤3,5	≤3,5	≤3,5
LINTING	LOG_{10} (Lint Count)	≤4,0	≤4,0	≤4,0	≤4,0
RESISTANCE TO LIQUID PENETRATION	Cm H_2O	≥20	≥10	≥100	≥10
BURSTING STRENGTH – DRY	kPa	≥40	≥40	≥40	≥40
BURSTING STRENGTH – WET	kPa	≥40	N/A	≥40	N/A
TENSILE STRENGTH – DRY	N	≥20	≥20	≥20	≥20
TENSILE STRENGTH – WET	N	≥20	N/A	≥20	N/A

CRITICAL AREA

LESS CRITICAL AREA

a Test conditions: challenge concentration 108 CFU/g talc. and 30 minutes vibration time.

b The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 BI are probably not different; materials varying by more than 0,98 BI probably are different. (The 95% confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives).

c For the purpose of this standard, log10 CFU ² 2 means maximum 300 CFU.

d BI = 6,0 for the purpose of this standard means: no penetration. BI = 6,0 is the maximum achievable value.

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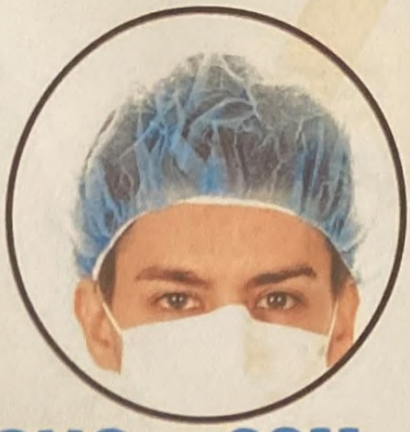

GNC - 2311
Head Cover

Nonwones spunband fabric
12 gr/m2
Elastic
500 pairs

GNC - 2411
Shoe Covers

%100 Polythene
Elastic (with mounth rubber)
500 pairs with package

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GENÇ

DISPOSABLE
CHEMICAL PROTECTION

Protection against infectious diseases such as COVID-19

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Workers may come into contact with biological substances in a wide range of situations. Appropriate personal protective equipment must be used to prevent potential infection.

Clothing designed to provide protection against infectious diseases establishes a physical barrier between the wearer's skin and the source of the infection, and prevents the disease from spreading to other people or environments.

Generally, micro-organisms such as bacteria, fungi and viruses are classed as biological substances. A detailed definition is provided in EU Directive 2000/54/EC. The crucial common denominator between all of these materials is that they can cause infections, trigger allergies, or produce a toxic effect.

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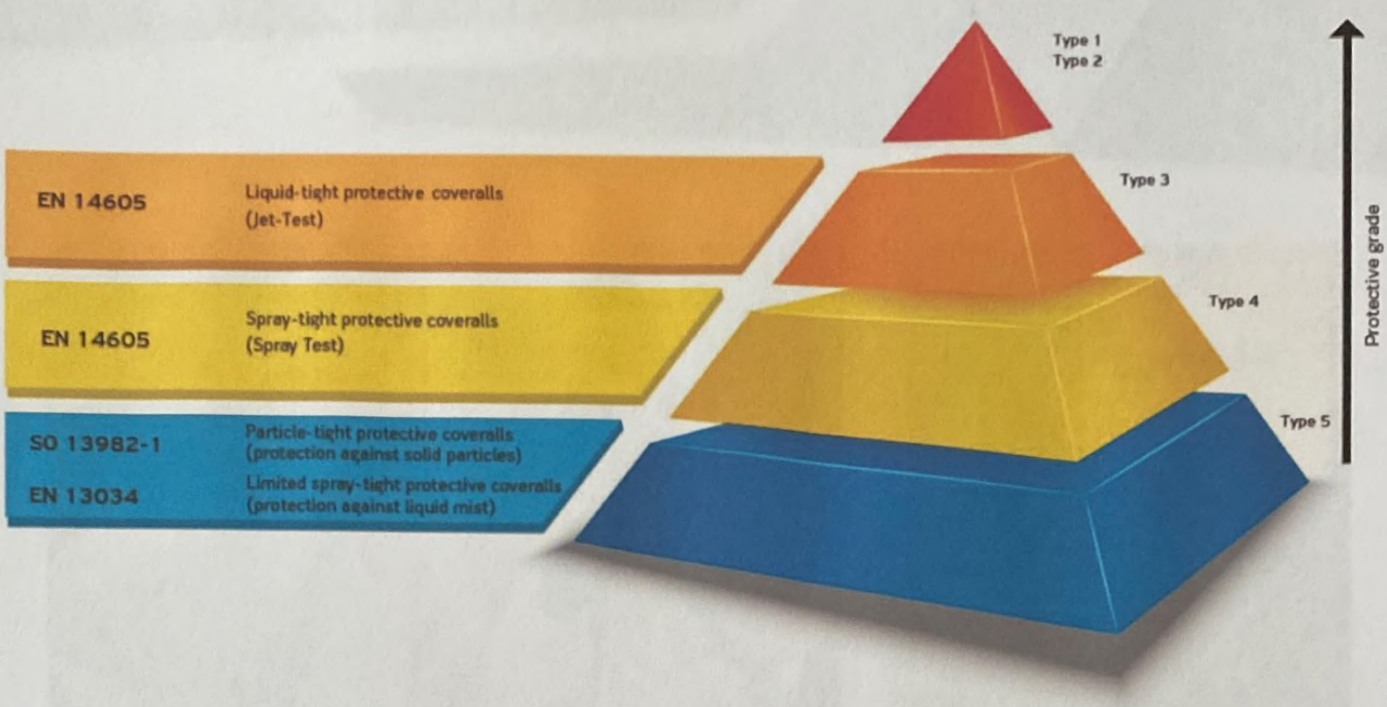

PPE Regulation EU 2016/425

The conditions for the sale of personal protective equip-ment (PPE) and the fundamental safety requirements that this PPE must meet are regulated in the PPE Regulation EU 2016/425.
If the requirements set out in the directive are met, the product is eligible for CE marking and can be offered for sale on the European internal market.

Depending on the level of risk that protective clothing is designed to protect against, PPE is assigned to one of three categories:

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1 CATEGORY 1
Simple protective equipment, low risk

2 CATEGORY 2
Protective clothing that protects the wearer against hazards; PPE that does not fall into category 1 or category 3

3 CATEGORY 3
Protective clothing that protects the wearer against potentially fatal hazards or serious and irreversible damage to health, high risk

GNC Protection Clothes comply with Category III Standards. Chemical protection is always classified as Category III.

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Protective clothing in accordance with EN 14126:2003

The EN 14126 standard defines the performance requirements for clothing designed to protect against infectious diseases. The defined test procedures focus on the medium that contains the micro-organisms, such as fluids, aerosols or solid dust particles. Due to the hetero-geneous nature of the micro-organisms, it is not possible to define performance criteria for them.

The tests stipulated by the standard relate only to the material; seam technologies are not taken into account. Taped seams provide a higher level of protection, as the micro-organisms are small enough to penetrate through the tiny needle holes along the seam.

The entire protective suit must also be certified as chemical protection clothing.

Wearing appropriate protective clothing does not provide complete, guaranteed protection against all chemical risks. It is also essential that you put on and remove the PPE correctly to ensure safety. Any person who assists in the removal of the clothing is also exposed to the risk of contamination.

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Product Features		GNC-2215	GNC-2213
EN 14605	Liquid-tight coveralls TYPE-3	✓	
EN 14605	Spray-tight coveralls TYPE-4	✓	
EN 13034	Limited spray-tight coveralls (protection against liquid mist) TYPE- 5	✓	✓
ISO 13982-1	Particle-tight coveralls (protection against solid particles) TYPE- 6	✓	✓
EN 1149-5	Protective clothing with antistatic properties (antistatic function only guaranteed if air humidity > 25%)	✓	✓
EN 14126	Protective clothing against infective agents	✓	✓
EN 1073-2	Protective clothing against particulate radioactive contamination (no protection against radioactive rays)	✓	✓

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Certificates

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