



PROUD TO PROTECT EVERYONE

**Controlled Contamination
Environments
PPE Selection Guide**



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Contamination-controlled environments

A controlled contamination environment or cleanroom is defined as an area or room within which there are constraints and limits on the concentration of biological contaminants and particulates.

Controlled contamination environments are used to protect certain products (e.g. electronic or pharmaceutical products) or people (e.g. operating theatres or aseptic patient rooms).

In order to operate within these environments, it is therefore necessary for staff to adopt particular protocols and use suitable clothing for this purpose.

Depending on the degree of cleanliness required, contamination-controlled environments are typically classified according to ISO 14644-1 and FED STD 209E as follows:

Class	Maximum number of particles per cubic meter of air						FED STD 209E Equivalence
	>0.1 µm	>0.2 µm	>0.3 µm	>0.5 µm	>1 µm	>5 µm	
ISO 1	10	2	-	-	-	-	
ISO 2	100	24	10	4	-	-	
ISO 3	1.000	237	102	35	8	-	Class 1
ISO 4	10.000	2.370	1.020	352	83	-	Class 10
ISO 5	100.000	23.700	10.200	3.520	832	29	Class 100
ISO 6	1.000.000	237.000	102.000	35.200	8.320	293	Class 1,000
ISO 7				352.000	83.200	2.930	Class 10,000
ISO 8				3.520.000	832.000	29.300	Class 100,000
ISO 9				35.200.000	8.320.000	293.000	Ambient air

Another classification of the degree of cleanliness of a clean room is related to the presence or absence of personnel inside it and is typically defined in grades from A to D and divided into At rest, in the absence of personnel and when machinery is stationary, and Operational (In Operation) if there is the presence of personnel and machinery carrying out their daily activities.

The degree of cleanliness is thus reclassified, considering the conditions under which the concentration of airborne particulate matter is detected, as follows:

Degree	>0.5 µm		>5 µm		Equivalent Class	
	At Rest	Operational	At Rest	Operational	At Rest	Operational
A	3.520	3.520			ISO 5	ISO 5
B	3.520	352.000		2900	ISO 5	ISO 7
C	352.000	3.520.000	2.900	29.000	ISO 7	ISO 8
D	3.520.000		29.000		ISO8	

From the table above it can be seen that the contamination coming from people and material inside the clean room is extremely relevant for the purpose of keeping it within the limits imposed by the processing and how it is not possible, for example, to assume the human presence in cleanliness classes from ISO 1 to ISO 4 which, in fact, They are only reached through special isolators and are typical of the processing of microprocessors in a vacuum environment

Use of PPE in controlled contamination environments

There are situations in which operators called upon to work in controlled contamination environments must in turn protect themselves from exposure to chemical agents potentially dangerous to their health and therefore must use suitable and adequate PPE (Personal Protective Equipment).

Therefore, a typical product for controlled contamination environments will have low particulate release characteristics and at the same time requirements for category III PPE for the protection of the person.

Particle Release Measurement

Particle release analysis for PPE may vary depending on the nature of the product.

If, for example, the product is of the “reusable” type, the most significant test is the Helmke drum that simulates the movement of a washing machine by shaking them and can thus determine how many fibers can be released into the environment because they are stressed by the washing process.

On the other hand, the approach to disposable garments is different, in which there is no component of repeated mechanical stress as in the case of washing.

From a comparison with international notified bodies, about the correct parameter to determine the release of particles into the environment, it has been ascertained that the test method of the ISO 9073-10 standard regarding dry linting is the most suitable for disposable protective clothing.

To determine their compliance with use in aseptic environments, it is appropriate to refer to the technical standard EN 13795, which regulates the use of protective gowns in the medical and surgical field, which sets a limit to particulate contamination.

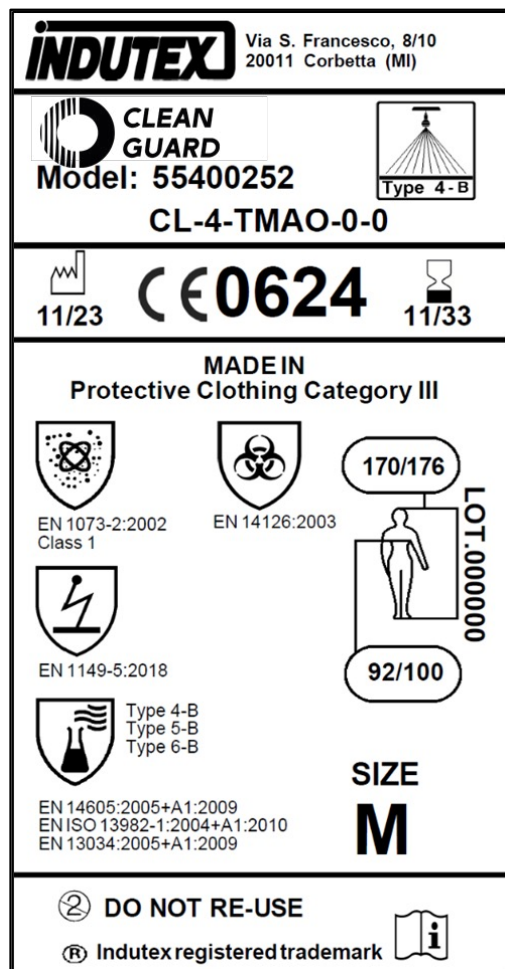
Given the affinity between a sterile surgical field for the protection of the patient and the environment classified for the preservation of the pharmaceutical product, it can be asserted that the limit established for surgical gowns regarding dry linting can also be assumed for environments with controlled contamination.

The Linting Coefficient CL ($\log_{10}$ Linting) < 4 is then established as a limit parameter, as indicated in the standard.

PPE Certification

All garments offered by Indutex for controlled contamination environments are certified as Category III PPE; therefore, they are subject to periodic checks by notified bodies, as per Regulation (EU) 2016/425 and their performance requirements have been verified by external accredited laboratories.

Below is an example of Category III CE marking and descriptions of the main certifications



• Certification for CHEMICAL PROTECTION

• Type 3 Certification

Garments with jet-tight connections
Checks according to EN 14605:2005+A1:2009 (equivalent to UNI EN 14605:2009).

• Type 4 Certification

Clothing with splash-proof connections.
Checks according to EN 14605:2005+A1:2009 (equivalent to UNI EN 14605:2009).

• Type 5 Certification

Protection from dispersed solid particles.
Tests according to EN ISO 13982-1:2004 +A1:2010 (equivalent to UNI EN ISO 13982-1:2011).

• Type 6 Certification

Limited protection against liquids.
Tests according to EN 13034:2005 +A1:2009 (equivalent to UNI EN 13034:2009).

• Certification for NUCLEAR PROTECTION:

For protective clothing against contamination by radioactive particles. Requirements and test methods for non-ventilated protective clothing against radioactive contamination in the form of particles. Checks according to EN 1073-2:2002 (equivalent to UNI EN 1073-2:2003).

• Certification for BIOLOGICAL PROTECTION:

Performance requirements and test methods for protective clothing against infectious agents. Checks according to EN14126:2003/AC:2004 (equivalent to UNI EN 14126:2004). If biological protection is also offered, the suffix -B will also be added to the wording (e.g. Type 4-B)

• Certification for ANTI-STATIC PROPERTIES:

Checks according to EN 1149-5:2018 (equivalent to UNI EN 1149-5:2018).
Electrostatic properties. Part 5: Design and material performance requirements.

Sterilization of PPE

Two main methods can be used for the sterilization of PPE, namely:

- Accelerated Electron Sterilization (B-Rays)
- Ethylene Oxide (EO) Sterilization

Depending on the type of material and the composition of the items, the best method of sterilization is chosen in order to offer the appropriate SAL (Sterility Average Level) without compromising the protective characteristics of the fabric.

For treatment protocols, Indutex has defined a SAL of 10^{-6} (the most common value in the pharmaceutical world), which, according to table 5 of the harmonized standard UNI EN ISO 11137-2, considers the probability of finding 1 non-sterile unit in 1,000,000.

The sterilization processes are validated, and all documentation is shared in the Indutex Cloud (which can be consulted or downloaded), subject to registration and authorization.

In addition, Indutex, for continuous monitoring of the process, has developed a rationale that, according to the UNI EN ISO 11737-1, UNI EN ISO 11737-2 and PhEur standards, establishes periodic checks and controls.

Below is a summary table with the data collected about particle release, certification and sterilization methods suitable for the product lines that are also offered in a sterile version

Product Line	CL Result	Certification	Sterilization Method
Tyvek (100% HDPE)	2,1	Cat. III Type 4	Accelerated electrons (b-rays)
CLEANGUARD PE (100% HDPE)	2,5	Cat. III Type 4-b	Accelerated electrons (b-rays)
CLEANGUARD (PP + film PE)	2,7	Cat. III Type 4-b	Accelerated electrons (b-rays)
PROPGUARD (100% SMS)	2,5	Cat. III Type 5/6	Ethylene Oxide (EO)

Table 1: Product Lines and Particle Release

A new sterilization method (VHP Vaporized Hydrogen Peroxide) is in study, and it will be available soon for all the materials

Indutex product range for controlled contamination environments

Indutex can supply a wide range of Category III (serious risks) and Category I (minor risks) products to meet all needs, whether they are related to the protection of the person, whether they are predominant for the protection of the production process or even corollary such as clothing for external visitors. Below is a selection of products selected for these needs, which is obviously just an example.

Typical Applications

- Electronics & Semiconductor Manufacturing
- Pharmaceutical Manufacturing
- Food production
- Sanitary Isolation

Aseptic, Electronic and Pharmaceutical Environments

These environments are typically characterized by very stringent limits and typically require sterilized clothing with low particulate release characteristics.

Indutex can supply different materials with which it packages, in its certified laboratories and with its Topguard production method, multiple solutions in the form of kits typically consisting of:

- Mandarin collar jumpsuit
- Socks with non-slip soles
- Hood with integrated surgical or FFPx mask

Of course, accessories such as short sleeves and shoe covers and the individual components of the kit are also available, as well as kits comprising elements, depending on the request.

All items intended for sterilization are bagged in a double sealed envelope in an ISO 7 classified environment, under laminar flow hoods that guarantee minimum ISO 5 levels.

Both values were measured in Operational mode and according to ISO 14644-3

Below is a diagram of the proposed solutions and the environments where they are recommended

Product Line	CL Result	Certification	Sterilization Method	ISO 5	ISO 6	ISO 7	ISO 8
Tyvek (100% HDPE)	2,1	Cat. III Type 4	Accelerated electrons (b-rays)	V	V	V	V
CLEANGUARD PE (100% HDPE)	2,5	Cat. III Type 4-b	Accelerated electrons (b-rays)	V	V	V	V
CLEANGUARD (PP + film PE)	2,7	Cat. III Type 4-b	Accelerated electrons (b-rays)	V	V	V	V
PROPGUARD (100% SMS)	2,5	Cat. III Type 5/6	Ethylene Oxide (EO)	X	V	V	V

Table 2: Product Lines and Classified Environments

Pharmaceutical Powder Solution Preparation Environments and APIs

These environments are characterized by an airborne concentration of dust from active pharmaceutical ingredients which, if inhaled, can be harmful to the health of operators. Contamination of the body can also lead to secondary inhalation of the product and therefore it is advisable to protect not only the respiratory tract but the whole body.

Other scenarios involve the use of chemicals and/or solvents.

In these cases, the operator is directly exposed to contamination on both the surface of the body and the respiratory tract.

Indutex offers integrated solutions for the protection of the body and respiratory tract through ventilated suits with both engine air (PAPR) and mains air (Air-fed). Multiple variants are available depending on the type of work to be carried out and the chemical/biological risk to which you are exposed.

Product Line	Certification	Powders	Liquid aerosols	Pressurized liquids
SPRAYGUARD	Cat. III Type 4-b	V	V	X
SPRAYGUARD PE	Cat. III Type 4-b	V	V	X
JETGUARD	Cat. III Type 3-b	V	V	V
JETGUARD PLUS	Cat. III Type 3-b	V	V	V
JETGUARD HD	Cat. III Type 3-b	V	V	V
JETGUARD PLUS HD	Cat. III Type 3-b	V	V	V

Table 3 Product Lines and Chemical Contamination

The degree of protection of the garment and its suitability for use vary depending on the chemical agents it must resist.

As far as respiratory protection is concerned, if the use of a ventilated diving suit is not contemplated, Indutex also offers surgical masks of its own production for the protection of the external environment from human contamination or BLS filtering face masks for the protection of the respiratory tract of operators.

If the combination of protective suit and full-face mask with Indutex filters is required, it can offer its garment in combination with BLS full face masks and filters appropriate to the type of risk. Surgical masks and filtering face masks are also available in a sterile version with Ethylene Oxide with a study that proves their complete safety and compliance with all safety regulations.

Secondary environments with intermediate controlled contamination

These environments are characterized by the presence of constraints related to particulate contamination but do not require sterile clothing and therefore fall within a lower degree of cleanliness than aseptic ones.

For this type of environment, Indutex can offer both kits identical to those proposed for aseptic but non-sterilized environments and clothing and/or accessories such as overalls, gowns, jackets and trousers.

The entire range can be made with any raw material available, thus making the possibility of solutions very wide.

Maintenance of pharmaceutical plants

These environments are characterized by the presence of chemicals used for the cleaning and maintenance of pharmaceutical plants in addition to the presence of residues from pharmaceutical processing that precedes maintenance itself.

For this type of intervention, the range of garments to be used depends once again on the type of contaminant (chemical) used, its physical condition (solid, liquid or gaseous) and its concentration.

Depending on the risk, Indutex offers ventilated and non-ventilated solutions for both its own range of clothing and the BLS range of respiratory protection.

Operating rooms or hospital environment

These environments are characterized by the constraint of the asepsis of the operating field but also, in some cases, by the constraint of the protection of the operator (surgeon or other medical personnel) from biological contamination coming from the patient himself.

Think, for example, of isolation wards, infectious disease wards, or more recently Covid outbreak. In this type of risk, the main feature is the biological protection that the garment offers, and it is necessary to make an important premise on how to choose the most suitable garment.

HOW TO CHOOSE THE RIGHT BIOLOGICAL PROTECTION

Biological Protection: EN 14126

EN 14126 is the standard that collects all the tests and test methods for the determination of resistance to microbiological pathogens.

It includes a series of tests and an evaluation of each result on a scale of values where the value 1 means passing the test with minimum requirements and 6 (or 3 in some cases) means passing the test with maximum values.

For the evaluation of the characteristics and requirements of Personal Protective Equipment against biological risks, the following five tests have been identified, considered representative of the major risk situations that may arise:

- Blood Resistance (ISO 16603) – Preliminary Test
- Resistance to blood pathogens (ISO 16604)
- Resistance to penetration of infectious agents by contact (ISO 22610)
- Resistance to contaminated aerosols (ISO 22611)
- Resistance to contaminated particles (ISO 22612)

Depending on the performance of the tests, the materials are classified as follows:

	Blood	Pathogenic	Contact	Aerosol	Powders
Best	20 KPa	20 KPa	t >75 min.	log > 5	Log CFU ≤1
Good	14 KPa	14 KPa	60 < t ≤75 min.		
Limited	7 KPa	7 KPa	45 < t ≤ 60 min.	3 < Log ≤5	1 < log cfu ≤2
Limited	3.5 KPa	3.5 KPa	30 < t ≤ 45 min.		
Scarce	1.75 KPa	1.75 KPa	15 < t ≤ 30 min.	1 < Log ≤3	2 < log cfu ≤3
Scarce	0 KPa	0 KPa	t ≤ 15 min.		

Table 4: Guide to the Classification of Biological protection

Since there is considerable variability in performance, Indutex invites everyone to inquire about resistance to biological agents to be sure that the level of performance of the materials is appropriate to the work to be done.

Regarding exposure to viruses and pathogens, Indutex recommends clothing that has the “Best” level in the above scheme, i.e. that has few or no exposure limitations and that has at least a type 4 certification for resistance to liquid aerosols.

In these cases, Indutex offers the following range of products for biological protection.

Material	Certification	Pathogenic	Contact	Aerosol	Powders
SPRAYGUARD	Cat. III Type 4-b	20 KPa	t >75 min.	log > 5	Log CFU ≤1
SPRAYGUARD PE	Cat. III Type 4-b	20 KPa	t >75 min.	log > 5	Log CFU ≤1

And their sterile version

Material	Certification	Pathogenic	Contact	Aerosol	Powders
CLEANGUARD	Cat. III Type 4-b	20 KPa	t >75 min.	log > 5	Log CFU ≤1
CLEANGUARD PE	Cat. III Type 4-b	20 KPa	t >75 min.	log > 5	Log CFU ≤1

Visitors

Although no personal protection is provided for visitors as they are not allowed to enter controlled or contaminated areas, their clothing also serves to contribute to the cleanliness of the businesses or relatives they visit.

Indutex offers a series of polypropylene accessories both of its own production and imported and the brand new POLIGARD HD line in 100% HDPE for those who want a highly antistatic and extremely high quality garment.

For visitors to infectious disease wards, if there is a need for protection of the visitor as well, Indutex offers **SPRAYGUARD** suits and/or accessories, **CLEANGUARD** surgical masks and FFP2 or FFP3 BLS filtering face masks.

Quality

All PPE manufactured under the Indutex brand are subjected to strict quality controls to ensure that the product that reaches customers complies with all international standards.

The complex Indutex quality system allows complete traceability of products and is UNI EN ISO 9001 ed. 2015 certified.

Indutex is regularly inspected not only by the notified bodies responsible for quality system control and maintenance of product certifications, but also by its pharmaceutical customers, allowing a continuous evolution of company procedures.

Services Indutex S.p.A.

Consultancy

Indutex offers a free consulting service to indicate the best solution in its range of products. An interview and a meeting with one of our representatives will allow us to study a suitable solution tailored to the needs of individual customers. Indutex also offers a free consultation service for BLS products in synergy with the manufacturer.

On-line documentation

Indutex offers an online documentation service via its cloud platform.



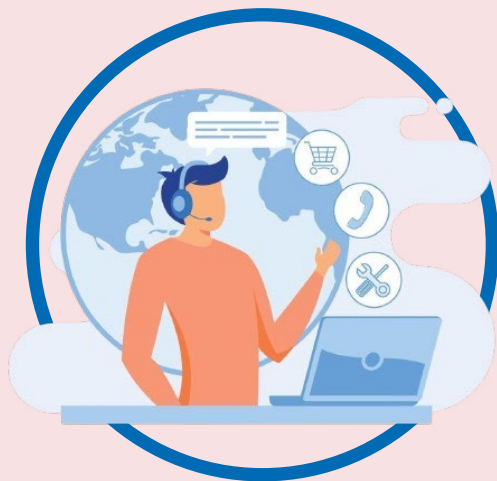
The link to access the cloud service is as follows:
<https://cloud.indutexspa.com/nextcloud/login>

After free registration, you will be able to access the part where you can consult certifications and other public material. It is possible, upon request after consultation and after authorization, to access the part reserved for the pharmaceutical world where it is possible to consult dedicated technical material.

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