



CATALOGUE

EQUIPMENT
FOR **LABORATORIES,**
CLEANROOMS
& **CONTROLLED**
ENVIRONMENTS.

summary

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About

Medicom Group

Founded in 1988 by Ronald Reuben, the Medicom® group is one of the world's leading manufacturers and distributors of high-quality single-use and preventive infection control products for the medical, dental and industrial markets. Present in more than 95 countries, Medicom has been a major player in the fight against epidemics and pandemics since its inception: HIV, avian flu, SARS, H1N1, Ebola and COVID-19.



VISION

Medicom® is the B-to-B partner, the expert who **develops, manufactures and sells** solutions that protect against and prevent contamination and infection.



MISSION

Medicom® **protects people and prevents risks** by listening, responding and anticipating customer needs, creating value through services and solutions that guarantee peace of mind and exceed customer expectations.



VALUES

- . Responsibility
- . Customer focus
- . Team spirit
- . Empathy
- . Sustainable development

CSR commitment

In line with Medicom®'s values for many years, we have chosen to structure our approach to society based on the fundamental principles of ISO 26000.

This means managing our environmental impact, the performance of our teams, the quality of our products and our commitment to our customers and partners in accordance with current standards and regulations.



Our mission is based on commitments that demonstrate our willingness to take responsibility for sustainable development.



OUR FIELDS

- **To provide a safe, motivating and sustainable working environment** for our employees.
- To introduce innovative, high-quality products to the market, while **minimising their impact.**
- **To exert a positive external influence** on the social, economic and environmental challenges of tomorrow.
- Encourage the development of a **sustainable value chain.**



Since 2023, we have also been committed to the **United Nations Global Compact's** Corporate Social Responsibility initiative, supporting its ten principles around human rights, labour standards, the environment and anti-corruption.

Over 100 years' experience.



History

- 1921 **FACTORY ESTABLISHED IN ANGERS**
 Specialized in cigarette paper manufacturing.
- 1972 **THE FIRST PAPER MASK**
 Kolmi® produces Europe's first paper mask — a revolutionary step in medical equipment.
- 1975 **THE FIRST NON-WOVEN MASK**
 Kolmi® designs the first single-use non-woven mask, combining protection and comfort.
- 1988 **FOUNDING OF THE MEDICOM® GROUP**
- 2003 **LAUNCH OF THE HOPEN BRAND**
 Specialist in single-use personal protective equipment (PPE).
- 2010 **FOUNDING OF KOLMI HOPEN®**
 Formed to offer complete head-to-toe protection solutions.
- 2011 **KOLMI HOPEN® JOINS THE MEDICOM® GROUP**
 A globally recognized dental equipment expert of Canadian origin.
- 2012 **FRENCH LEADER IN MEDICAL MASKS**
 Kolmi® becomes the first manufacturer to supply surgical masks to operating rooms across France.
- 2020 **NEW PARTNERSHIP WITH LOSER GMBH**
 Expansion in the dental sector across Europe through the acquisition of LOSER GMBH.
THE COVID-19 CRISIS
 A major turning point with a sharp increase in production to meet global demand.
- 2021 **LAUNCH OF MANIKHEIR**
 The first nitrile glove manufacturing plant in France.
SILVER ECOVADIS MEDAL
 A first recognition of our CSR (Corporate Social Responsibility) commitment.
- 2022 **STRATEGIC PARTNERSHIP WITH WEESAFE**
 Acquisition of WeeSafe, a recognized player in full-body protection with Category III PPE suits.
- 2023 **NEW IDENTITY!** kolmi hopen® continues its drive to create a European entity closely linked to the group by renaming itself Medicom SAS for the Medical/Industrial sector and Medicom GMBH for the Dental sector.
- 2024 **INAUGURATION OF THE 4 MANIKHEIR PRODUCTION LINES**, representing a capacity of over 900 million gloves per year.
Eco Vadis gold medal.

Sites



Expertise and production.



Medicom SAS

Saint-Barthélemy-d'Anjou (Maine-et-Loire)

Our first plant is the fruit of over 100 years' experience. Here, we develop and manufacture single-use protective equipment, DM and hygiene control devices, with a particular focus on controlled environments for respiratory protection.

At this plant, we design and produce high-quality medical masks, FFP masks, headgear, overshoes, dental bibs and care squares. Our Saint-Barthélemy-d'Anjou site is a symbol of our commitment to quality and innovation.

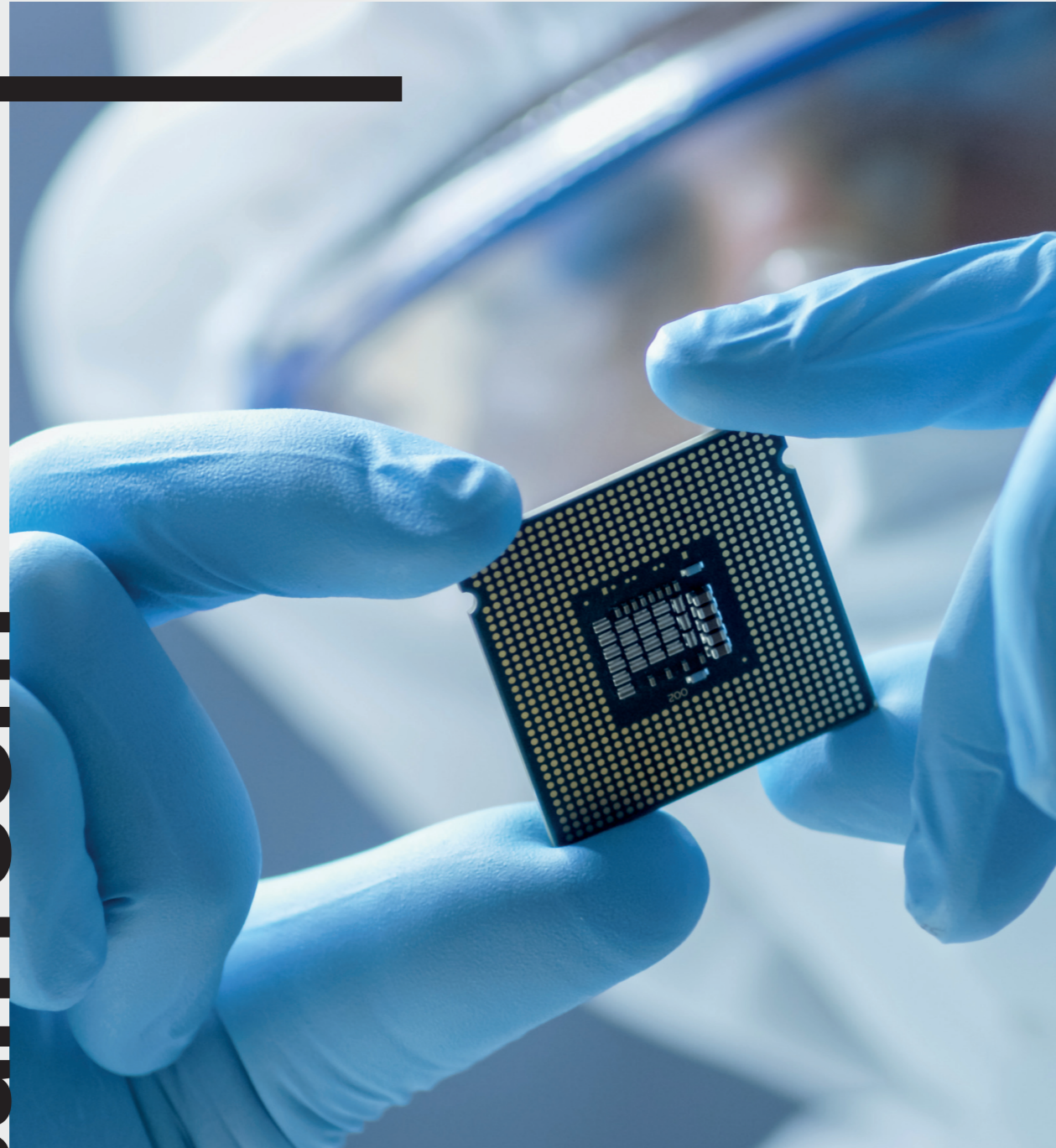
ManiKHeir

Bessé-sur-Braye (Sarthe)

Born in 2021, ManiKHeir embodies our vision of strengthening European sovereignty in the production of personal protective equipment. With a capacity to supply up to one billion single-use nitrile gloves, ManiKHeir's ultimate aim is to ensure sufficient stock levels to meet the global needs of the healthcare sector and sensitive industries.

This plant in Europe is tangible proof of our commitment to safety and preparation for the future, to ensure the availability of high quality products at all times.

Clean room



Cleanrooms, definition and standards.

CLEANROOM ACCORDING TO STANDARD **ISO 14644-1 (2016)**

Cleanrooms and related controlled environments provide the means to control air and, where appropriate, surface contamination to levels appropriate for contamination-sensitive activities.

Contamination control can be beneficial for product or process protection in applications such as **aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, food and biotechnology.**

In cleanrooms, one of the most important sources of contamination is the personnel working in them. It is **estimated that 75% of contamination in cleanrooms comes from operators.**

The purpose of cleanroom clothing is therefore to protect the product and its environment from contamination generated by personnel. In fact, as specified in appendix B of standard EN ISO 14644-5, the primary function of cleanroom clothing or equipment is to act as a barrier filter protecting products and processes from human contamination. It is therefore important to note that the primary purpose of cleanroom clothing is not to protect the user. This function will be performed by Personal Protective Equipment (PPE), which will have this dual function.

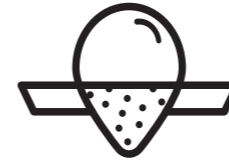
Source :
 ISO 14644-1(2016): Cleanrooms and related controlled environments - Part 1: classification of air particulate cleanliness.
 ASPEC Guide - Clothing and accessories for cleanrooms and controlled environments

Selecting the right equipment.



How can the risk of contamination in controlled environments be eliminated?

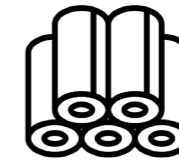
By selecting equipment, particularly masks and coveralls, with low particle emission and designed for operator comfort.



GUARANTEEING FILTRATION AND PARTICLE RETENTION CAPACITY

Helmke Drum cleanliness assessment according to the IEST-RP-CC003.4 method

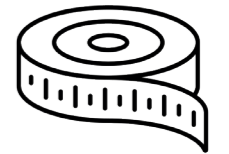
- Ensuring mask compatibility with ISO 3 Class A and + environments
- Ensuring suit compatibility in ISO 4 class environments



SELECTING MATERIALS THAT MEET REQUIREMENTS AND ARE COMFORTABLE FOR THE WEARER

Use of materials with low particulate emission that are comfortable for the operator

- Lightweight
- Safe



ENSURING THAT THE ITEM IS MADE TO SUIT PROTOCOLS AND THE OPERATOR

Design technology to make the items easy to put on and remove and keep the operator comfortable in their breathing and movements

- Different types of attachments and shapes for masks
- Adapted to dressing protocols
- Ergonomically designed coveralls



GUARANTEEING PROPER PRODUCT PACKAGING

Ultra-clean packaging, adapted to the protocol

- Each product is individually packaged
- Double or triple bagging in grouping boxes
- Sealed bag



GOING FURTHER IN PROTECTION

By choosing products with additional standards relating to Personal Protective Equipment and by choosing sterilised products for certain needs.

75%

of contamination in cleanrooms comes from operators.

100 MILLIONS

is the number of bacteria contained per gram of saliva and sputum.



QUICK AND EASY TO PUT ON



EXCEPTIONALLY BREATHABLE



EXCELLENT FILTRATION



USE IN ROOMS CLASSIFIED ISO 3 CLASS A AND +



SOFTEX TECHNOLOGY



MASS BALANCE TECHNOLOGY



Face protection.

In cleanrooms, masks are mainly used to protect the wearer's environment, but they can also provide protection for the user, as is the case with our FFP masks (category III PPE).

Thanks to Softex technology and its very low-release materials, the ISO AIR range has been specially designed to ensure user comfort and environmental protection. With results in excess of 99%, ISO AIR masks provide excellent bacterial, particulate and viral filtration, while offering breathable comfort for the wearer.

Lastly, Medicom is the first company to have developed a range of masks made from recycled materials, thanks to the Mass Balance approach.

The entire ISO AIR range has been tested on the Helmke drum using the IEST-RP-CC003.4 method to ensure very low particle release.

ISO AIR masks can therefore be used in Class A ISO 3 and + environments.



The **Mass Balance**

approach is a unique process that enables recycled materials to be mixed with fossil materials at the start of the production chain, while retaining identical properties.

As a result, some of our masks are made from 70% recycled materials, while maintaining filtration capacity and excellent comfort for the wearer.

To find out more about the Mass balance approach, please contact us.

Face protection.

Non-sterile masks

HEADLOOPS NON STERILE - PLEATED SHAPE

MADE IN FRANCE



- Designed for use in ISO 3 Class C environments
- Excellent filtration efficiency (BFE, PFE, and VFE > 99%)
- Easy to put on and increased comfort thanks to headloops
- Available in two sizes : M = 210 x 90 mm / L = 230 x 90 mm

REF.				
60.701-30		230 x 90 mm	Double packed	6 x 50 u

HEADLOOPS NON STERILE - PLEATED SHAPE

MADE IN FRANCE



- Designed for use in ISO 3 Class C environments
- Excellent filtration efficiency (BFE, PFE, and VFE > 99%)
- Easy to put on and increased comfort thanks to headloops
- Available in two sizes : M = 210 x 90 mm / L = 230 x 90 mm

REF.				
60.702		210 x 90 mm	Double packed	6 x 50 u

HEADLOOPS NON STERILE - "DUCKBILL" SHAPE

MADE IN FRANCE



- Designed for use in ISO 3 Class C environments
- Excellent filtration efficiency (BFE, PFE, and VFE > 99%)
- Great breathability thanks to the large breathing chamber
- Two sizes available : M = 240 x 100 mm / L = 268 x 115 mm

REF.				
60.754L		268 x 115 mm	Double packed	6 x 50 u
60.754M		240 x 100 mm		

» DID YOU KNOW?

1. In controlled environments, it's vital that the mask is adapted to the wearer's face and covers the entire face so that the skin and potential hairs are not visible. **The two sizes in the ISO AIR range meet this essential criterion!**

> **99%**
BFE . PFE . VFE

Excellent efficiency, filtration, of bacteria, particles and viruses.



Developed from material derived from **RECYCLING**

EARLOOPS NON STERILE

MADE IN FRANCE



- Designed for use in ISO 5 Class C environments
- Excellent filtration efficiency (BFE, PFE, and VFE > 99%)
- Soft, non-irritating elastics
- Two sizes available : M = 175 x 90 mm / L = 195 x 90 mm

REF.				
60.712L		195 x 90 mm	Double packed	8 x 50 u
60.712M		175 x 90 mm		

TIE-ON NON STERILE

MADE IN FRANCE



- Low particulate release - Tested on Helmke drum
- Excellent filtration efficiency (BFE, PFE, VFE > 99%)
- Two sizes available : M = 175 x 95mm / L = 195 x 95mm

REF.				
60.720L		195 x 95 mm	Double packed	6 x 50 u
60.720M		175 x 95 mm		

Manufactured in our plant in France


2. The delta P or differential pressure test is a method of measuring the ease with which air passes from one side of a mask to the other. In practical terms, it measures how easy it is for a wearer to breathe through a mask. The lower the score, the more breathable the mask. This parameter is tested in the standard governing Medical Device masks (EN 14683:2019) and must not exceed 60 Pa/cm².

*The % of recycled material used may vary depending on the model. Please refer to the technical data sheet.

Face protection.

Sterile mask

HEADLOOPS STERILE






 MADE IN FRANCE



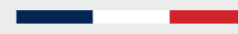
ISOAIR®

STERILE EO

- Use in ISO 3 Class A environments
- Sterility Assurance Level 10
- Tested before and after sterilization, filtration performance (BFE, PFE, VFE > 99%) and comfort remain strictly identical
- Sterilization process according to ISO 11135 standard governing ETO sterilization of healthcare products
- Optimal fit and adjustment thanks to the headloops
- Excellent breathability

REF.				
60.702-STE		210 x 90 mm	Double packed	6 x 50 u

Manufactured and sterilised in France



> 99%
BFE . PFE . VFE
 Excellent efficiency, filtration,
 of bacteria, particles
 and viruses.


50% RECYCLED
 material

» DID YOU KNOW?

Widely used for the sterilisation of medical devices, **ETO sterilisation maintains filtration performance and comfort before and after sterilisation.**

This 60.702-STE mask has been sterilised in accordance with a strict qualification procedure governed by standard ISO 11135, which regulates ETO sterilisation of medical devices.

Face protection.

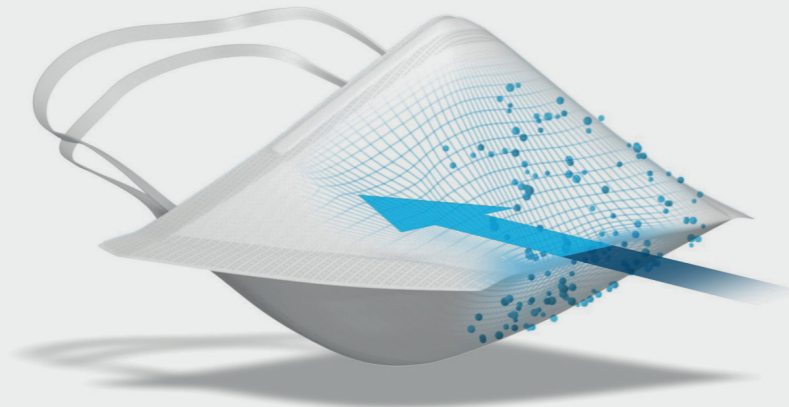
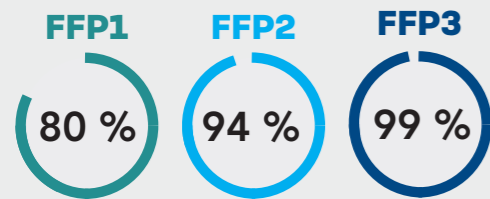
FFP mask

Respiratory protection masks are category III Personal Protective Equipment (PPE) which covers the mouth, nose and chin. FFP stands for Filtering Face Piece, and they protect the wearer from inhaling airborne droplets and particles, which can carry infectious agents or agents harmful to the body. FFP masks should therefore be used when protection of the wearer takes precedence over protection of the environment.

The role of respiratory protection masks is to:

- Protect the wearer from airborne particles.
- There are 3 levels of airborne particle filtration efficiency.
- Standard EN 149:2001+A1:2009
- Regulation EU 2016/425

Minimum filtration of FFP masks:



Kolmi®
Oxygen

Manufactured in our plant in France



» **70%**
recycled-origin materials
using the Mass Balance
approach.

Kolmi®Oxygen FFP masks are also certified as a Class I Medical Device under EU Regulation 2017/745 and EN 14683:2019+Ac:2019. With three sizes available, the Kolmi®Oxygen range ensures a perfect fit for different facial morphologies.

FFP1 NR D TYPE IIR

MADE IN FRANCE



Kolmi®
Oxygen

MD Class I

PPE CAT. III

REF.				
M51014-WH-MB	M	Box	10 x 50 u	
M51014S-WH-MB				

FFP3 NR D TYPE IIR

MADE IN FRANCE



Kolmi®
Oxygen

MD Class I

PPE CAT. III

REF.				
M53214-WH-MB	S	Box	10 x 50 u	
M53214S-WH-MB				
M53014-WH-MB	M	Box	10 x 50 u	
M53014S-WH-MB				
M53114-WH-MB	L	Box	4 x 50 u	
M53114S-WH-MB				

FFP2 NR D TYPE IIR

MADE IN FRANCE



Kolmi®
Oxygen

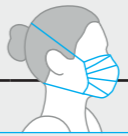
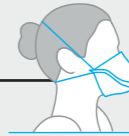

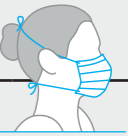
MD Class I

PPE CAT. III

REF.				
M52214-WH-MB	S	Box	10 x 50 u	
M52214S-WH-MB				
M52014-WH-MB	M	Box	10 x 50 u	
M52014S-WH-MB				
M52114-WH-MB	L	Box	4 x 50 u	
M52114S-WH-MB				

Selecting the right protective mask.

SELECTION CHART

					
		ORIGAMI FOLD WITH HEADLOOPS	DUCKBILL MASK WITH HEADLOOPS	TILE FOLD WITH ELASTIC EAR LOOPS	TILE FOLD WITH TIES-ON
FOR PROTECTING THE ENVIRONMENT AND THE PRODUCT	Easy to put on	●	●	●	
	Optimum comfort	●	●		
	Recommended for long-term use	●	●		
	Excellent filtration capacity	●	●	●	●
	Sizes & References	M 60.702 L 60.701-30 M 60.702-STE	M 60.754M L 60.754L	M 60.712M L 60.712L	M 60.720M L 60.720L
FOR PROTECTING THE WEARER & THE ENVIRONMENT	FFP 1 NR D	M	M51014S-WH-MB	M51014-WH-MB	
			FFP 2 NR D	S	M52214-WH-MB
	M	M52014-WH-MB			M52014S-WH-MB
		L		M52114S-WH-MB	M52114S-WH-MB
	FFP 3 NR D			S	M53214-WH-MB
		M			M53014-WH-MB
				L	M53114-WH-MB



Body protection.

COVERALLS

Coveralls are the first barrier against particulate contamination. As humans are the main source of contamination in controlled environments, it is estimated that a person walking at normal speed emits almost 7.5 million particles larger than 0.3 µm if they are not equipped with suitable clothing.

So what solutions are there to protect the environment, processes and products from this potential contamination?

Today's cleanroom operators can choose between two solutions: reusable garments, usually made of polyester, and short-use garments. However, the performance of these two solutions varies considerably in terms of both particle filtration and environmental impact.

Size chart

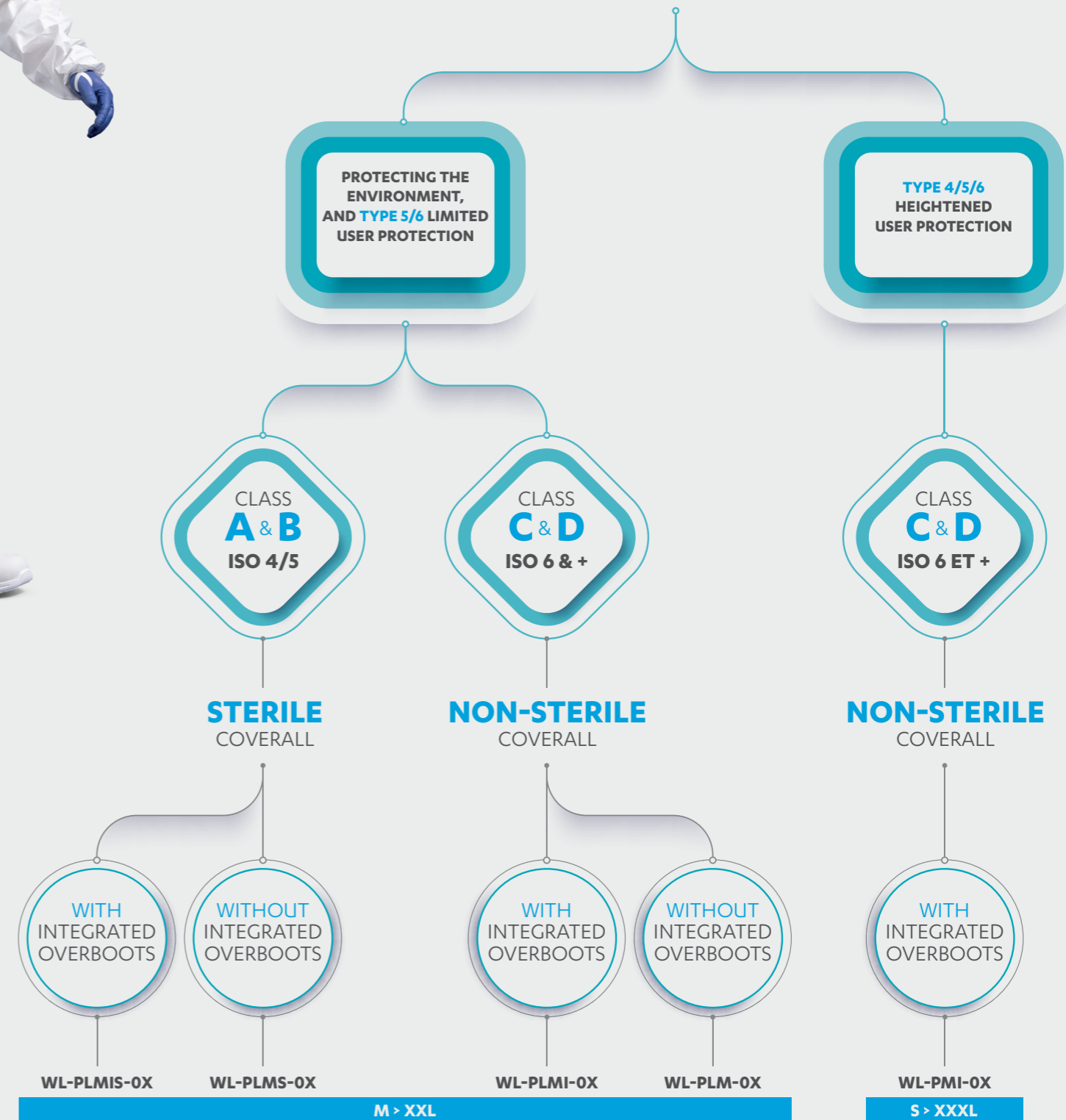
SIZE	REF. WEESAFE	HEIGHT	CHEST MEASUREMENT
S	01	162 - 170 cm	84 - 92 cm
M	02	170 - 176 cm	92 - 100 cm
L	03	176 - 182 cm	100 - 108 cm
XL	04	182 - 188 cm	108 - 116 cm
XXL	05	188 - 194 cm	166 - 124 cm
XXXL	06	194 - 200 cm	124 - 132 cm



Selecting the right protective overall.



WHAT TYPE OF PROTECTION IS NEEDED?



TYPE OF ENVIRONMENT ACCORDING TO ISO AND GMP STANDARDS

REF & SIZES

STANDARDS GUIDE

CATEGORY III CHEMICAL PROTECTION ACCORDING TO REGULATION EU 2017/745

TYPE 6 EN 13034 LIMITED LIQUID SPLASHES	TYPE 3 EN 14605 HEAVY LIQUID SPLASHES
TYPE 5 EN ISO 13982-1 SOLID CHEMICAL PARTICLES	TYPE 1 & 2 EN 943-2 AEROSOLS AND NOT GAS TIGHT
TYPE 4 EN 14605 LIQUID AEROSOLS	

ADDITIONAL STANDARDS :

EN 1149-5 ELECTROSTATIC RISKS
EN 1073-2 RADIOACTIVE PARTICLES
EN 14126 INFECTIOUS AGENTS

coverall

FILTRATION PERFORMANCE & PARTICLE RETENTION

The filtration capacity of cleanroom garments can be measured using the BFE (Bacterial Filtration Efficiency) test method, which is also used for measuring the filtration of masks. Several studies have shown that reusable cleanroom garments are 30% less efficient than limited-use coveralls made from SMS/Microporous materials.

In addition to filtration performance, cleanroom clothing must not be a source of contamination. This is why particulate release remains an essential selection criterion. Repeated washing and sterilisation (by gamma radiation) of reusable garments directly affects the structure of fibres and molecules. Their reuse must therefore be limited in order to avoid excessively high levels of particulate release and significantly degraded filtration and retention capacity.

AN ENVIRONMENTAL IMPACT THAT RAISES QUESTIONS

The environmental impact of cleanroom clothing is an increasingly important criterion during qualification processes. At first glance, one could think that limited-use garments have a much higher environmental impact than reusable clothing. However, reusable garments travel repeatedly between their place of use and their place of washing and sterilisation, which obviously affects their carbon footprint. Thus, laundry products and washing & drying processes are an additional consideration to take into account, since their environmental impact can be significant. It is therefore important to take account of the whole product life cycle, from designing to disposal or recycling, in order to assess the environmental impact of cleanroom clothing.

Protection

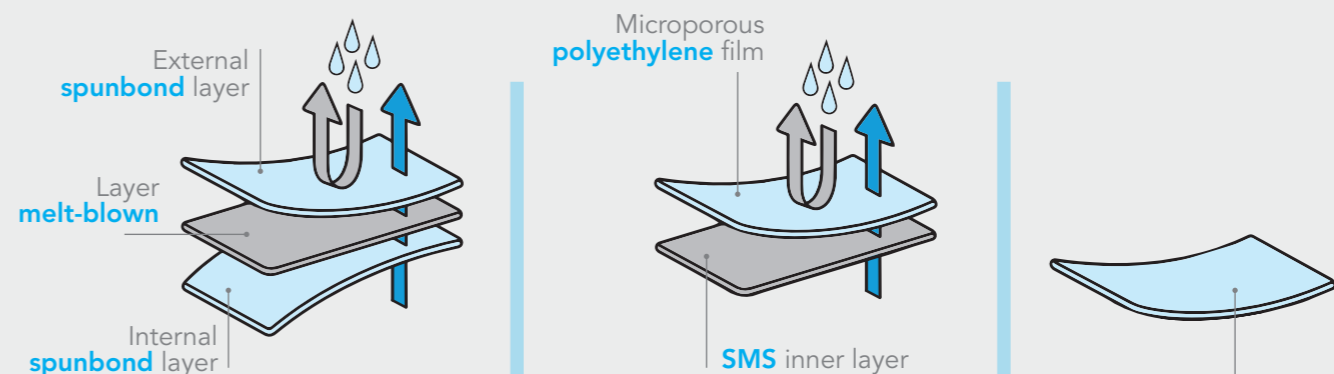
Increased operator protection with Type 5/6 coveralls. Unlike reusable clothing, limited-use coveralls are CAT III Personal Protective Equipment. They therefore protect the user from chemical risks. Even if their role is above all to protect the product/process from the worker, they can in certain cases be useful, in particular when handling chemicals or when there is a biological risk.

Sources :
C. Moschner, Contamination Source "Human" or how efficient is Cleanroom Garment, 2017

Potnis, S. P., Shetty, S. M., Rao, K., N., and Prakash, J. "Studies in Effect of Gamma Radiation on Synthetic Fibres - I." Die Angew. Makromol. Chem. 6 (1969)

Our range & main applications

Our Category III coveralls are designed to meet the requirements of a wide range of industries and professions, in particular for use in protected environments (Helmke drum test for particle release). They are made from an SMS non-woven fabric with a laminated PE film for protection and comfort.



SMS is a non-woven fabric which, thanks to its meltblown layer, provides a barrier against solid particles while also offering protection against small splashes of liquids. Highly breathable, SMS also provides comfort for the user by releasing accumulated perspiration.

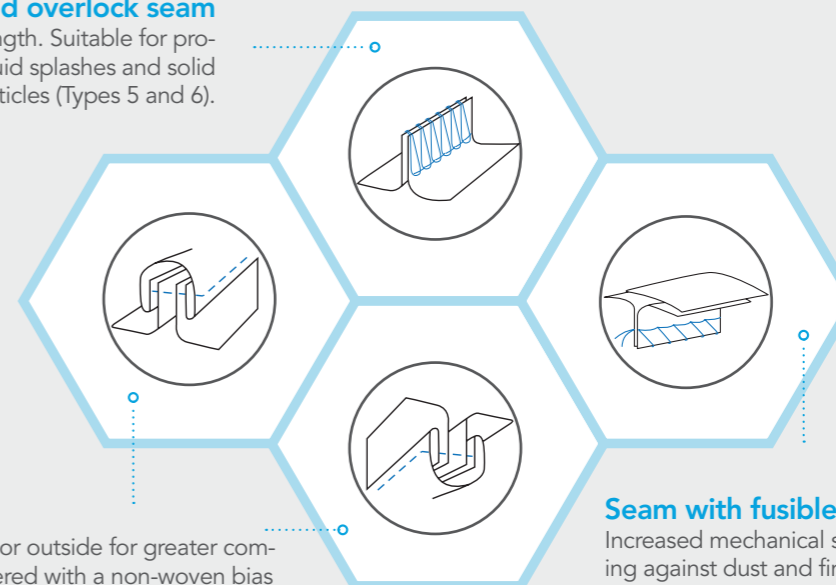
To enhance protection against chemical sprays, we have added a laminated microporous polyethylene film to the SMS layer, providing a real barrier while maintaining an optimum level of comfort. This material is also lint-free and tear-resistant.

High-density PE barrier film for maximum waterproofing against dense liquid splashes.

Depending on their level of protection and their application, our models are made with different seams:

4-thread overlock seam

Good mechanical strength. Suitable for protection against light liquid splashes and solid particles (Types 5 and 6).



Edged seam

Can be edged on the inside or outside for greater comfort, this type of seam is covered with a non-woven bias for absolute mechanical resistance while guaranteeing a very good seal.

Seam with fusible web

Increased mechanical strength and waterproofing against dust and finer particles. Mandatory under the French decree of 07 March 2013 on exposure to asbestos.

Body protection.



The WeePro Labo® range has been specially designed to meet the needs of cleanroom workers. Made from our new Micromium® material, it helps control contamination while providing comfort and breathability to the user. The whole range has undergone Helmke Drum cleanliness testing and is available in sterile and non-sterile versions as required.

sterile

WEEPRO LABO TYPE 5, TYPE 6 - STERILE - INTEGRATED BOOT COVERS



PPE CAT. III



STERILE R

- MICROMIUM® material with very low contamination
- Garment with ergonomic and comfortable fit: elastic cuffs, ankles, and waist - Integrated overshoes with sole
- Triple packaging: Carton with a sealed bag of 25 units - 1st packaging with «Easytear» system - 2nd packaging vacuum-sealed individual pouch - Sterile
- Bound seams, tunnelled elastics, and thumb loops

WEEPRO LABO TYPE 5, TYPE 6 - STERILE



PPE CAT. III



STERILE R

- MICROMIUM® material with very low contamination
- Garment with ergonomic and comfortable fit: elastic cuffs, ankles, and waist
- Triple packaging: Carton with a sealed bag of 25 units - 1st packaging with «Easytear» system - 2nd packaging vacuum-sealed individual pouch - Sterile
- Bound seams, tunnelled elastics, and thumb loops

REF.		G/M2		
WL-PLMIS-02	M	60	Triple packed	25 x 1 u
WL-PLMIS-03	L			
WL-PLMIS-04	XL			
WL-PLMIS-05	XXL			

REF.		G/M2		
WL-PLMS-02	M	60	Triple packed	25 x 1 u
WL-PLMS-03	L			
WL-PLMS-04	XL			
WL-PLMS-05	XXL			

MICROMIUM SERIE

non-sterile

WEEPRO LABO TYPE 5, TYPE 6



PPE CAT. III



- MICROMIUM® material with very low contamination
- Clothing with ergonomic and comfortable fit: elasticated cuffs, ankles, and waist
- Triple packaging: Carton with a sealed bag of 25 units - 1st packaging with «Easytear» system - 2nd packaging vacuum-sealed individual pouch
- Bound seams, tunnelled elastics, and thumb loops

REF.		G/M2		
WL-PLM-02	M	55	Triple packed	25 x 1 u
WL-PLM-03	L			
WL-PLM-04	XL			
WL-PLM-05	XXL			

WEEPRO LABO TYPE 5, TYPE 6 - INTEGRATED BOOT COVERS



PPE CAT. III



- MICROMIUM® material with very low contamination
- Garment with ergonomic and comfortable fit: elasticated cuffs, ankles, and waist - Integrated overshoes with sole
- Triple packaging: Carton with a sealed bag of 25 units - 1st packaging with «Easytear» system - 2nd packaging vacuum-sealed individual pouch
- Bound seams, tunnelled elastics and thumb loops

REF.		G/M2		
WL-PLMI-02	M	60	Triple packed	25 x 1 u
WL-PLMI-03	L			
WL-PLMI-04	XL			
WL-PLMI-05	XXL			

Find our sterile accessories on pages 35 and 42

Body protection.

In controlled atmosphere areas, when there is an increased risk for workers, it is necessary to provide them with appropriate coveralls that meet strict worker protection standards while ensuring low particulate release to continue to protect the environment.

WEEPRO MAXINTEGRAL TYPE 6, TYPE 5, TYPE 4



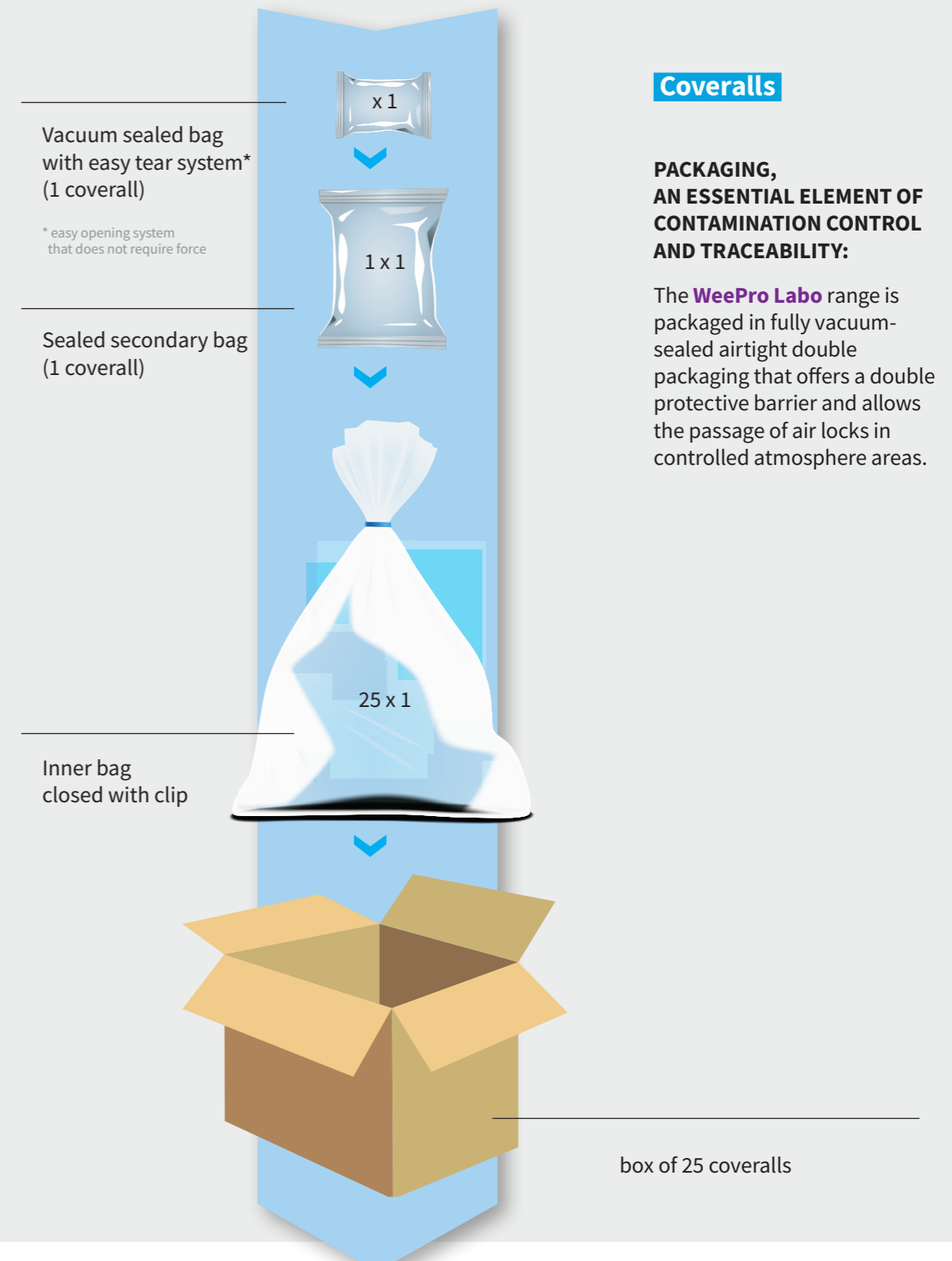
PPE CAT. III



- Breathable material
- Heat-sealed seams waterproof to very fine particles, liquids and aerosols
- Tested against biological risks
- Integrated overshoes

REF.		G/M2		
WL-PMI-01	S	63	Polybag	50 x 1 u
WL-PMI-02	M			
WL-PMI-03	L			
WL-PMI-04	XL			
WL-PMI-05	XXL			
WL-PMI-06	XXXL			

Packaging & Traceability



Coveralls

PACKAGING, AN ESSENTIAL ELEMENT OF CONTAMINATION CONTROL AND TRACEABILITY:

The **WeePro Labo** range is packaged in fully vacuum-sealed airtight double packaging that offers a double protective barrier and allows the passage of air locks in controlled atmosphere areas.

Body protection.

Gowns

Made from non-leaching materials, short-use gowns are designed to limit contamination in controlled areas. Individually packaged, they prevent cross-contamination and are an excellent alternative to overalls when full protection is not required.

CHEMICAL PROTECTIVE GOWN WEEPRO TYPE PB 6



PPE CAT. III



- Material with very low fluffiness
- Jersey cuffs
- Available in 4 sizes

REF.			G/M2		
WL-BE-02		M	63	Polybag	50 x 1 u
WL-BE-03		L			
WL-BE-04		XL			
WL-BE-05		XXL			

HYGIENE GOWN MICROPOROUS COLLAR SNAP FASTENER



- imper-respirant
- with PE film for better sealing
- elasticated cuffs
- suitable for controlled environments with limited fiber particle release
- antistatic

REF.			G/M2		
40.550/02		M	60	Polybag	50 x 1 u
40.550/03		L			
40.550/04		XL			
40.550/05		XXL			

HYGIENE GOWN MICROPOROUS COLLAR ZIP



- imper-respirant
- with PE film for better waterproofing
- elasticated cuffs
- suitable for controlled environments with limited fiber particle release
- antistatic

REF.			G/M2		
40.507/03		L	60	Polybag	50 x 1 u
40.507/04		XL			
40.507/05		XXL			
40.507/06		XXXL			

Body protection.

Sleeve

SLEEVES WEEPRO TYPE PB 6



PPE CAT. III



- Highly waterproof material for liquid splashes
- Non-linting material to prevent contamination in controlled areas
- Antistatic treated material on both sides facilitating the dissipation of electrostatic charges

REF.			G/M2		
WL-ME-00		One size	63	Polybag	1 x 200 u

POLYPROPYLENE SLEEVE + POLYETHYLENE COATING



- PP coated PE
- Better waterproofing
- Reduced fiber release
- Suitable for protected environments

REF.			G/M2		
20.400		One size	45	Polybag	10 x 100 u

WEEPRO LABO SLEEVE - STERILE



PPE CAT. I

STERILE R

- Made from Micromium, non linting material
- Helmke Cat I drum
- Sterile

REF.			G/M2		
WL-MMS-00		One size	60	Triple packed	25 x 50 u


Body protection.

Caps

The first barrier against hair, our charlottes and their perfectly uniform veil retain any hair that may escape from styling products used in controlled environments.

Our Kolmi® range, manufactured in France at our Angers factory, is certified as a Class I Medical Device, guaranteeing superior cleanliness and quality.

CLIP CAP POLYPROPYLENE 10 G/M2







 MADE IN FRANCE



Kolmi®

MD Class I







- Comfortable, breathable, and highly stretchable to accommodate all hair types.
- Very durable.
- Latex-free.

REF.		G/M2		
C12004		10	Dispenser box	300 u
C12103				Polybag
C12513A				

CLIP CAP POLYPROPYLENE 12 G/M2







- Optimal support.
- Very covering.
- Latex-free

REF.		G/M2		
70.101		12	Polybag	10 x 100 u
70.102				
70.103				


CLIP CAP POLYPROPYLÈNE SMS 14 G/M2 53CM



- Double special comfort elastic.
- Very soft material in polypropylene SMS.
- Latex-free.

REF.		G/M2		
70.182		14	Polybag	10 x 100 u






CLIP CAP POLYPROPYLENE 15 G/M2

 MADE IN FRANCE




MD Class I

- Comfortable, breathable and very stretchy.
- Very resistant.
- Latex-free.

REF.		G/M2		
C12501A		15	Polybag	12 x 100 u
C12511A				







CLIP CAP POLYPROPYLENE 15 G/M2

 MADE IN FRANCE



MD Class I






- Comfortable, breathable and very stretchy.
- Very resistant.
- Latex-free.

REF.		G/M2		
C12001		15	Dispenser box	200 u
C12101				
C12201				

BEARD COVER POLYPROPYLENE 10 G/M2



- Covers the lower part of the face perfectly.
- Provides suitable protection for controlling the environment against beard hair falling.

REF.		G/M2		
70.801		10	Polybag	10 x 100 u
70.802				

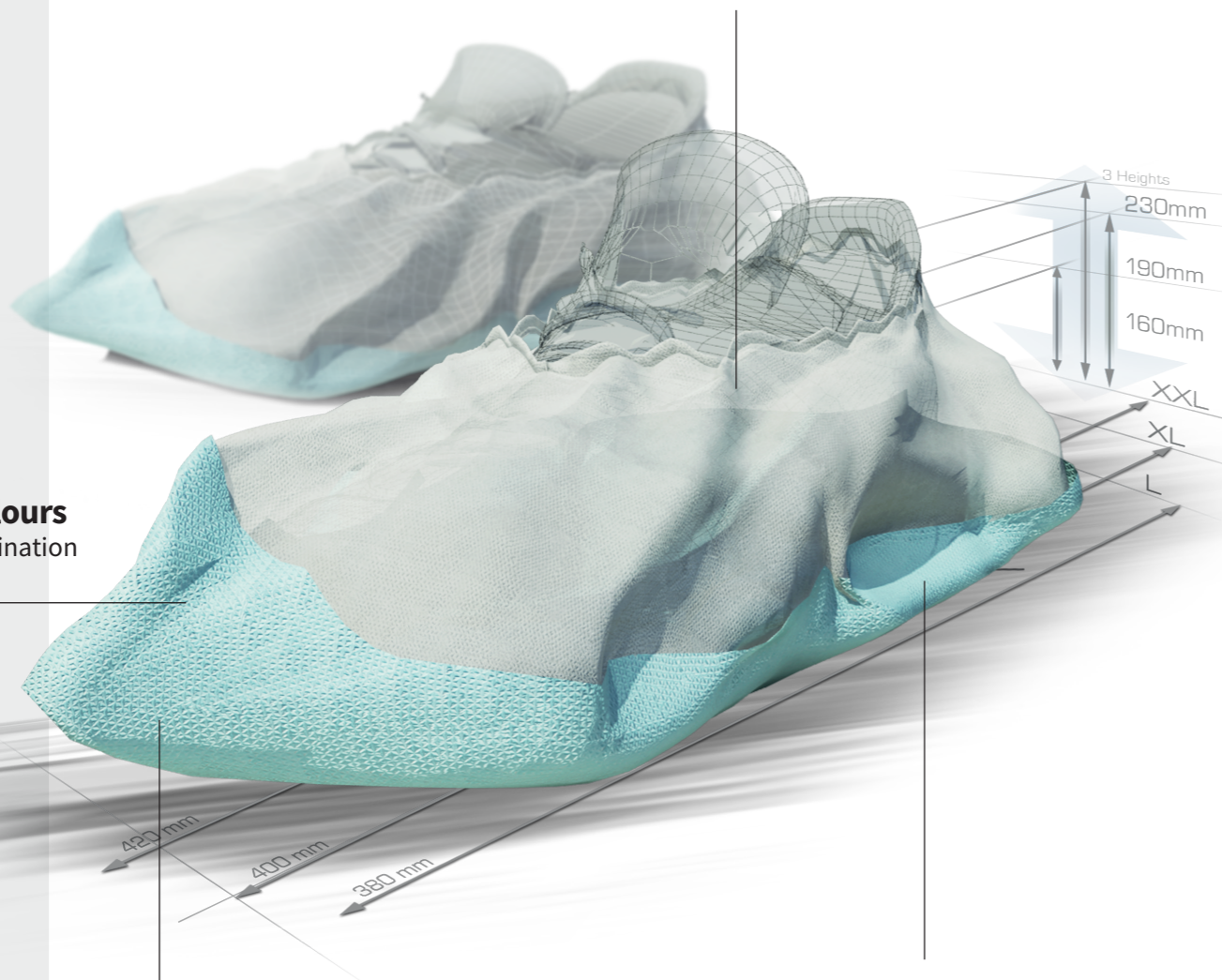
Simple and quick to put on

A wide choice of colours
to prevent cross-contamination

A wide choice of sizes
3 different heights and 3 lengths

Anti-slip and water-repellent technology

Kolmi® & Kolmi®
Isoguard Skidguard



Foot protection.

Overshoes & Overboots

Our overshoes with our Kolmi®Skidguard and Kolmi®Isoguard anti-slip technologies are made in France.

They protect the environment while guaranteeing user safety.

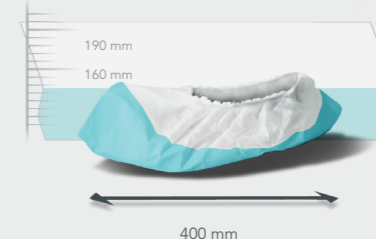
Our Kolmi®Isoguard range has been specially designed for controlled environments thanks to its 80µm sole. Tested on the Helmke Drum, they provide the best results in terms of particle release.

The different sizes

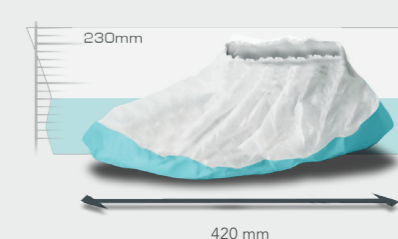
Standard L
fits shoe sizes 35-41



Taille Universelle XL
fits shoe size 42-45



Taille XXL
fits shoe size 46-49



Want to spot
overshoes made
from recycled
materials?

**LOOK OUT
FOR THE LOGO!**



NEW RANGE OF OVERSHOES MADE FROM RECYCLED MATERIALS

Our overshoes made in France are evolving and now include a significant proportion of recycled materials in their composition.

We've worked hard to offer you eco-designed overshoes that guarantee the same robustness and anti-slip performance:

- 100% PP overshoes without sole made from 90% recycled materials
- PP overshoes + sole made from at least 60% recycled materials

Foot protection.

Overshoes

RECYCLED SHOECOVER WITH SOLE SIZE XL

MADE IN FRANCE

Kolmi®
Skidguard



MD Class I

PPE CAT. I

- The shoe cover is made up of 60% recycled material
- Anatomical shape adapted to all types of shoes and morphologies
- Elastic band for ankle support
- Non-slip sole

REF.	Icon	G/M2	Icon	Icon
10.040R	XL	90	Bag	1 x 400 u

SHOE COVER WITH SOLE SIZE XXL

MADE IN FRANCE

Kolmi®
Skidguard



MD Class I

- Waterproof and non-slip sole 60 µm
- Ankle support elastic
- Very large size model
- Recommended for long-term use

REF.	Icon	G/M2	Icon	Icon
10.007/XXL	XXL & very tall height	35	Bag	1 x 300 u

RECYCLED SHOECOVER WITH SOLE SIZE XL

MADE IN FRANCE

Kolmi®
Skidguard



MD Class I

PPE CAT. I

- The shoe cover is made up of 60% recycled material
- Anatomical shape adapted to all types of shoes and morphologies
- Elastic band for ankle support
- Non-slip sole

REF.	Icon	G/M2	Icon	Icon
10.041R	XL	90	Bag	1 x 400 u

SHOE COVER WITH SOLE SIZE XL

MADE IN FRANCE

Kolmi®
Skidguard



MD Class I

- Waterproof and non-slip sole 60 µm
- Ankle support elastic band
- Suitable for all body types and all types of shoes
- Recommended for long-term use

REF.	Icon	G/M2	Icon	Icon
10.005V				1 x 200 u
10.006	XL	30	Bag	1 x 400 u
10.007				

RECYCLED SHOECOVER WITHOUT SOLE SIZE L

MADE IN FRANCE

Kolmi®



MD Class I

PPE CAT. I

- The hydrophobic spunbond of the shoe cover is made from 90% recycled material
- Anatomical shape adapted to all types of shoes and body shapes.
- Elastic band for ankle support

REF.	Icon	G/M2	Icon	Icon
10.001D-10	XL	30	Bag	1 x 500 u

SHOE COVER WITH REINFORCED SOLE SIZE XL

MADE IN FRANCE

Kolmi®
Isoguard



- With reinforced plasticized sole PE 80 µm
- Ideal for clean environments as low particle release
- For all types of shoes
- Recommended for very long-term use

REF.	Icon	G/M2	Icon	Icon
10.005	XL	30	Bag	1 x 200 u
10.008				1 x 400 u

RECYCLED SHOE COVER WITHOUT SOLE SIZE L

MADE IN FRANCE

Kolmi®



MD Class I

PPE CAT. I

- The hydrophobic spunbond of the shoe cover is made from 90% recycled material
- Anatomical shape adapted to all types of shoes and body shapes.
- Elastic band for ankle support

REF.	Icon	G/M2	Icon	Icon
H01038A	L	30	Dispenser box	1 x 500 u

SAFEGEAR® ESD SHOECOVER WITH CONDUCTIVE STRIP

SafeWear®



- ESD Protection: Conductive strip dissipating electrostatic charges to protect sensitive components
- Polypropylene (PP) Material: Lightweight, breathable, and dust-resistant for optimal comfort
- Ease of Use: Adjustable elastic for quick application and a secure fit
- Hygiene and Safety: Ideal for clean environments, preventing contamination from footwear

REF.	Icon	G/M2	Icon	Icon
10.035	One size	115	Polybag	25 x 40 u

Foot protection.

Overshoes & Overboots

OVERSHOES WEEPRO TYPE PB 6



PPE CAT. III



- Sole with a strong non-slip power
- Material with very low fluffiness
- Two sizes available

REF.			G/M2		
WL-CCE/AD-LXL		L-XL	63	Polybag	20 x 20 u
WL-CCE/AD-SM		S-M			

OVERBOOTS WEEPRO TYPE PB 6



PPE CAT. III



- Sole with a strong non-slip power
- Material very slightly fluffy
- Two sizes available

REF.			G/M2		
WL-CBE/AD-LXL		L-XL	63	Polybag	15 x 20 u
WL-CBE/AD-SM		S-M			

STERILE WEEPRO LABO OVERBOOTS



PPE CAT. I

STERILE R

- Made from Micromium, non-linting material
- Helmke Drum cat I
- Sterile

REF.			G/M2		
WL-CBEMS-00		One size	60	Triple packed	50 x 2 u





Hand protection.

Did you know?

The **IEST-RP-CC005.4** standard sets out detailed test procedures for evaluating **single-use gloves** in controlled environments. It focuses on crucial criteria such as **cleanliness and physical and chemical integrity**. Among the tests included are **the assessment of particle release, extractables, non-volatile residues (NVR)**, as well as the detection of contaminants such as silicone or dioctyl phthalate (DOP) using infrared spectroscopy (FTIR). These tests ensure that the gloves meet the stringent requirements of sensitive industries such as pharmaceuticals and electronics, minimising cross-contamination and preserving the purity of the working environment. Thanks to this standard, the gloves offer optimum protection while helping to maintain strict cleanliness conditions in areas such as cleanrooms.



GUARANTEE THE CONTROL OF CONTAMINANTS IN CONTROLLED ENVIRONMENTS

- Compliance with the various regulations and standards in force (DM and/or PPE) according to the specific needs of each application.
- Analysis of particulate contamination and extractables in accordance with IEST-RP-CC005.4.
- Evaluation of electrostatic properties in accordance with EN 1149-1/2/3.

Hand protection.

Gloves.



Safety and Compliance in Controlled Environments

Single-use gloves are used in cleanrooms and controlled environments for a number of key reasons:

- **Protection of workers:** To guarantee the health and safety of people working in these environments.
- **Maintaining cleanliness:** Ensuring the integrity of the production process and product quality by avoiding contamination.

The gloves used must meet strict criteria to comply with Good Manufacturing Practice (GMP) and other international standards. The aim is to reduce the risks and costs associated with contamination by external agents.

Contamination Risks and Types of Protection

To ensure total protection in sensitive environments, gloves must be adapted to the different types of contamination risks:

- **Particulate contamination:** Skin flakes, hairs and other fine particles must be effectively blocked to guarantee product integrity.
- **Microbiological contamination:** Hand flora and the transmission of micro-organisms require gloves designed to prevent microbiological contamination.
- **Chemical and molecular contamination:** Traces of grease, sweat and other substances can compromise product safety. Our gloves provide a barrier against these risks.
- **Protection against electrostatic discharge (ESD):** In certain industries or applications, electrostatic discharge can harm sensitive equipment. ESD gloves offer effective protection against this type of risk.

Double Gloving: An Enhanced Solution for Protection

Safety requirements can also include **double gloving**, a common practice in operations where additional protection is required, particularly in environments where contamination is **particularly risky**. In this context, gloves are often designed with longer, fitted cuffs to cover the sleeve of laboratory coats or cleanroom suits, providing **continuous protection** and avoiding exposure of the wrist or forearm.

Our Commitments: Safety, Compliance and Performance

Laboratory gloves play a key role in minimising the risk of contamination and ensuring the reliability of results while maintaining a safe and compliant working environment.

At **Medicom**, we understand the critical importance of protection in high-risk environments.

We are **committed** to providing single-use laboratory gloves **of the highest quality**. All our products are manufactured under a rigorous **ISO 13485 and ISO 9001** certified quality system, ensuring compliance with the most stringent international standards.

Depending on the specific needs of each application, our gloves also **comply with various regulations and technical standards**, guaranteeing maximum safety for operators while preserving the integrity of the products handled. Thanks to our innovative solutions and long-standing expertise, we are committed to providing laboratory gloves that support both **safety and efficiency in the most demanding environments**.

Hand protection.

Gloves

KOLMI COVERFEEL TOUCH

MADE IN FRANCE



Kolmi®
Coverfeel Touch

MD Class I

PPE CAT. III



- Great elasticity & optimal comfort.
- Excellent grip on objects.
- Recommended in medical, industrial, and agri-food environments.
- Made in France.

REF.	Size	Dispenser box	Quantity
1140-A	XS	Dispenser box	10 x 100 u
1140-B	S		
1140-C	M		
1140-D	L		10 x 90 u
1140-E	XL		
1140-F	XXL		

* All types of food

KOLMI COVERFEEL CARE

MADE IN FRANCE



Kolmi®
Coverfeel Care

MD Class I

PPE CAT. III



- Great elasticity & optimal comfort.
- Excellent grip on objects.
- Recommended for medical, industrial, and food environments.
- Made in France.

REF.	Size	Dispenser box	Quantity
1142-B	S	Dispenser box	10 x 100 u
1142-C	M		
1142-D	L		
1142-E	XL	10 x 90 u	
1142-F	XXL		

* All types of food

KOLMI COVERFEEL CARE LONG

MADE IN FRANCE



Kolmi®
Coverfeel Care Long

MD Class I

PPE CAT. III



- Great elasticity & optimal comfort.
- Excellent grip on objects.
- Long cuff.
- Recommended for medical, industrial, and food environments.
- Made in France.

REF.	Size	Dispenser box	Quantity
1144-B	S	Dispenser box	10 x 100 u
1144-C	M		
1144-D	L		
1144-E	XL	10 x 90 u	
1144-F	XXL		

* All types of food



SAFETOUCH® X'TRA



SafeTouch®
X'tra

PPE CAT. III



- Dexterity and optimal comfort
- Long cuff 355 mm
- Double chlorination
- Recommended in nuclear laboratories against contamination by radioactive particles

REF.	Size	Polybag	Quantity
30.350N/S	S	Polybag	5 x 100 u
30.350N/M	M		
30.350N/L	L		
30.350N/XL	XL		

HIGH RISK PVC GLOVE

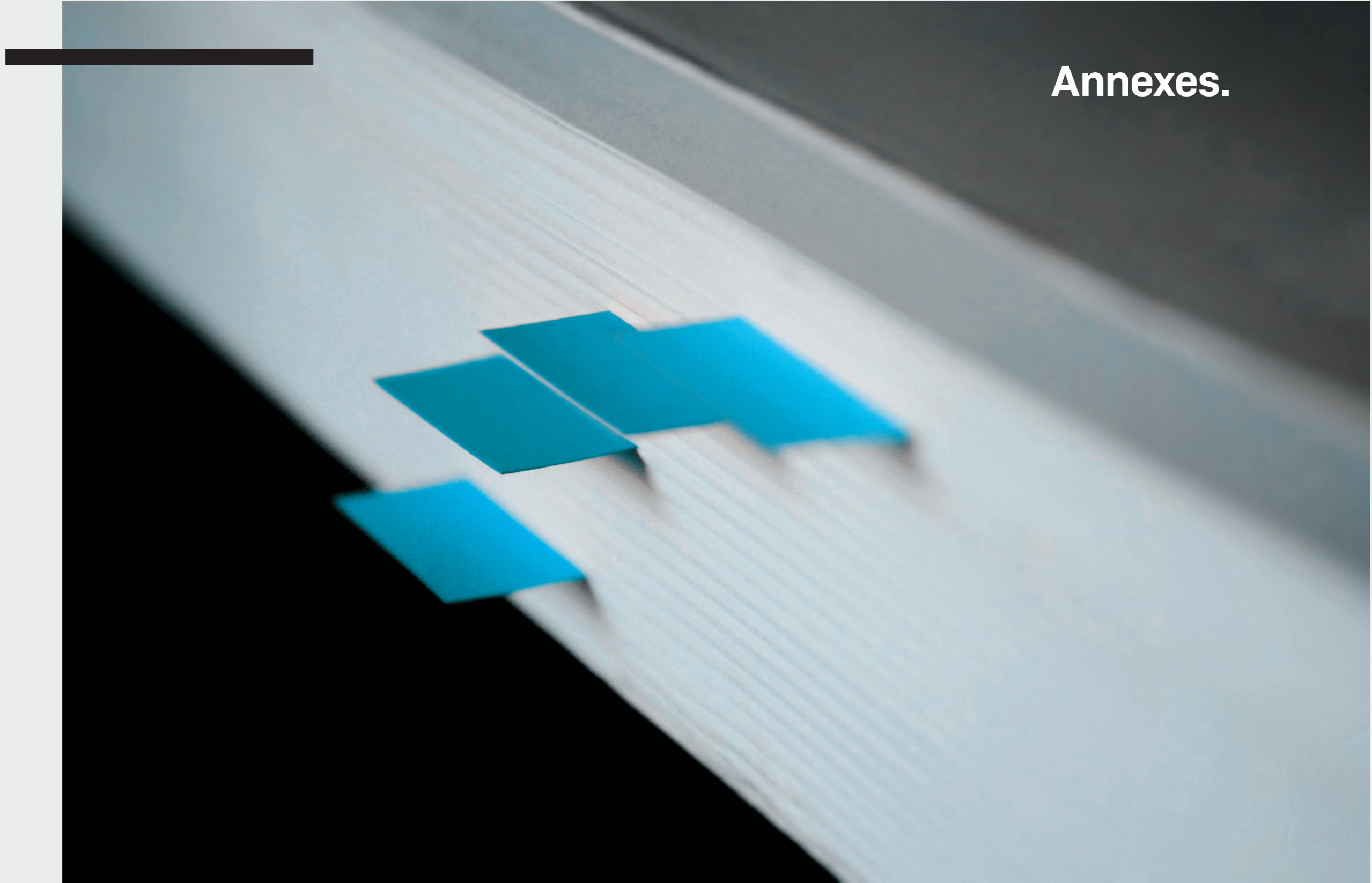


PPE CAT. III



- The PVC glove is designed to protect hands against mechanical and chemical hazards.
- The glove is made of white PVC with a long translucent PVC cuff 400 mm long.
- The glove is waterproof and airtight.
- It is particularly recommended for use in the chemical industry, maintenance and heavy industry: agriculture, construction, waste collection, laundry and industrial cleaning.

REF.	Size	Polybag	Quantity
30.G52N/S	S	Polybag	100 x 2 u
30.G52N/M	M		
30.G52N/L	L		
30.G52N/XL	XL		



Annexes.

ANNEX 1

**CONTROLLED PARTICULATE RELEASE,
AN ESSENTIAL ELEMENT OF CONTAMINATION CONTROL.**

The cleanliness of clean rooms and controlled environments is primarily classified by their particulate concentration, i.e. the number of particles of a certain size found in a given volume of air. Today there are two globally recognized classification systems: ISO 14644-1 and GMP (Good Manufacturing Practices) Annex 1 used in the pharmaceutical industry.

These two classification systems govern the maximum acceptable concentration of particles per m³ of air. Different particle sizes can be taken into account (from 0.1µm to 5.0µm).

One major difference between these two systems lies in the fact that the GMPs specify not only the maximum authorized concentration when the cleanroom is in operation (i.e. during the production phase) but also when it is idle (i.e. when manufacturing is not in progress).

PARTICULATE CLEANLINESS CLASSES FOR CLEAN ROOMS ACCORDING TO ISO 14644-1:

ISO Classification	Maximum permitted particulate concentration per m3 according to the following sizes					
	0,1µm	0,2µm	0,3µm	0,5µm	1,0 µm	5,0 µm
ISO 1	10	2	-	-	-	-
ISO 2	100	24	10	4	-	--
ISO 3	1 000	237	102	35	8	-
ISO 4	10 000	2 370	1 020	352	83	-
ISO 5	100 000	23 700	10 200	3 520	832	29
ISO 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO 7	-	-	-	352 000	83 200	2 930
ISO 8	-	-	-	3 520 000	832 000	29 300
ISO 9	-	-	-	35 200 000	8 320 000	293 000

Source: Standard ISO 14644-1

PARTICULATE CLEANLINESS CLASSES OF CLEANROOMS ACCORDING TO PHARMACEUTICAL GMPs:

GMP categories	Maximum permitted particulate concentration per m3 according to the following sizes			
	Idle		Active	
	0,5µm	5,0 µm	0,5µm	5,0 µm
A	3 520	20	3520	20
B	3520	29	352 000	2 900
C	352 000	2 900	3 520 000	29 000
D	3 520 000	29 000	-	-

Source: Good Manufacturing Practices Annex 1

In order to make it easier to compare these two tables, companies producing in cleanrooms can refer to the correspondence table below allowing a simple comparison between GMP classes and ISO classes.

GMP classes	GMP classes	
	Idle	Active
Class A	ISO 4.8	ISO 4.8
Class B	ISO 5	ISO 7
Class C	ISO 7	ISO 8
Class D	ISO 8	-

Explanation of ISO 4.8: In class A, no more than 20 particles of 5.0µm are acceptable per m³. However, in ISO class 4, particles of 5.0 µm are not taken into account as they are too large and in ISO class 5, up to 29 per m³ are tolerated. This is why class 4.8 makes it possible to place class A in relation to the ISO standard between class 4 and 5. This is only a means of comparison and in no way a class of the ISO 14644-1 standard.

Source: PIC/S Guide to Good Manufacturing Practice, Annex 1 – Manufacture of Sterile Medicinal Products, version 14, clause 4.

NATURE AND SIZES OF CONTAMINANTS FREQUENTLY ENCOUNTERED IN CLEANROOMS:

The vast majority of particles emitted in clean rooms are linked to humans. They mainly come from the skin by the phenomenon of desquamation (loss of dead skin), hair (eyelashes and hair) and the emission of droplets from the mouth and nose. They may also come from the shedding of fibres by the clothes used in the clean room. There are two types of particle: inert particles and viable particles. Viable particles are those that can be a source of biocontamination, which are particularly monitored in the field of health, while inert particles are not a source of biocontamination.

CLEANROOM CLOTHING AS THE MAIN MEANS TO CONTROL PARTICULATE CONTAMINATION:

Cleanroom clothing means all the items that form a barrier between the operator and the product/environment for which the operator could be a source of particulate or biological contamination. Cleanroom clothing must therefore have intrinsic filtration capabilities; at the same time, it must not itself generate particles or fibres. In order to assess that potential particulate release from cleanroom clothing, there are different methods including the Helmke Drum test and the body box test.

Helmke Drum test according to recommendation IEST-RP-CC003.4

The purpose of this test is to measure the number of particles released by an item of cleanroom clothing (gown, coverall or hood) by simulating the movements of an active operator. The item of clothing to test is placed in a previously decontaminated stainless steel drum whose internal atmosphere is of ISO 5 class. For 10 minutes, at a rate of 10 revolutions per minute, the drum performs different rotation movements that make the clothing item release the particles contained in it. A particle counter precisely and objectively quantifies the particles of sizes equal to or greater than 0.3 and 0.5 µm that have been released during the test.

The results obtained are to be compared with the table below in order to be able to place the item of clothing in recommendation IEST-RP-CC003.4:

Category	Clothing items	Particle emission rate (particles/min)	
		≥ 0,3 µm	≥ 0,5 µm
I	1 x frock 1 x coverall 3 x hoods	< 1 700 < 2 000 < 780	< 1 000 < 1 200 < 450
II	1 x frock 1 x coverall 3 x hoods	1 700 à 17 000 2 000 à 20 000 780 à 7 800	1 000 à 10 000 1 200 à 12 000 450 à 4 500
III	1 x frock 1 x coverall 3 x hoods	17 000 à 170 000 20 000 à 200 000 7 800 à 78 000	10 000 à 100 000 12 000 à 120 000 4 500 à 45 000

Sources: IEST-RP-CC003.4 classification

It must be noted that only hoods, coveralls and frock are taken into consideration in the reading table above. However, it is easy to compare other items such as masks or overshoes by taking into account the material surface in m² of each of the items.

Analysis of results obtained:

The primary purpose of this test is to be able to correlate the cleanroom clothing item with use in one of the ISO classes. Generally, category I is recommended for environments of class 7 or below, and category II for ISO classes 7 to 9. For its part, category III is not taken into account in controlled environments.

Body box (or dispersion chamber) test:

A body box is a test bench for measuring all the particles released by cleanroom clothing worn by an individual in real conditions. It is made up of a controlled atmosphere booth classified ISO 4 or below, and its purpose is to make a person perform various codified movements for 10 minutes in order to reproduce an activity in real conditions. Thanks to a unidirectional downward vertical flow, the released particles are sent to a particle counter in order to quantify them precisely. It is one of the most representative and most useful tests for evaluating different cleanroom garments, in particular for comparing the results of reusable and disposable clothing.

ANNEX 2

GMP ANNEX 1 UPDATE.

On 25 August 2022, the new version of Annex 1 of Good Pharmaceutical Manufacturing Practices (GMPs) was published, with an application deadline of 25 August 2023.

In Europe, GMP annex 1 provides the general guidance that is to be used for the manufacture of all sterile medicinal products. However, some principles and guidelines can be used to support the manufacture of other products which are not intended to be sterile, such as certain liquids, creams, ointments and intermediate biological products with low microbial loads, but where the control and reduction of microbial and particulate contamination are believed to be important.

This update reflects the wish to continually strengthen user safety and thus ensure overall safety throughout the life cycle of the product, that is to say from its design to its release in the market. That safety reinforcement particularly involves Quality Risk Management (QRM). The update emphasises that this method of risk management must be taken into account at each stage of the life of the product and that it “must provide an objective and scientific means of identifying, assessing and guaranteeing the potential risks of contamination of products and processes”. All the risk analyses must therefore be carried out periodically in order to enable the parties involved to review their performance all the time.

Another major change is related to the Contamination Control Strategy (CCS). Indeed, the reference to the CCS is mentioned throughout Annex 1. As with Quality Risk Management, the CCS must be applied at each stage of the product life cycle. However, one of the new features is that a global CCS will have to be set up at the manufacturing site level in order to present the company's overall strategy to limit the risk of contamination.

Standard ISO 14644 is also mentioned throughout Annex 1. Indeed, it details the importance for manufacturers to control their environment, particularly in respect of particulate contamination. That entails continuous monitoring and control of the release and diffusion of inert (non-viable) particles and viable particles while complying with the standards of ISO 14644.

Biocontamination control requires very good management of aseptic behaviour and the sterile barrier. Personnel accessing Grade A and B areas must be trained in the procedures and must be able to assess the compliance of their equipment. Periodic reassessments must be carried out. In Grade A and B rooms, sterile equipment must become the norm and regular samples must be taken to check compliance.

In conclusion, this update of GMP Annex 1 reinforces control and the adoption of strategies, particularly in order to reduce the risks of biocontamination and particulate contamination. This reinforcement, added to the risk analysis at every stage of the product life cycle, serves the sole purpose of guaranteeing and reinforcing the safety of patients and users.



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EQUIPMENT
FOR **LABORATORIES,**
CLEANROOMS
& **CONTROLLED**
ENVIRONMENTS.

