

MANUFACTURER'S INSTRUCTIONS AND INFORMATION

Gown: Protective Gown

PLEASE READ THESE INSTRUCTIONS CAREFULLY

Current legislation (L. Decree 81/2008) assigns responsibility for identifying and choosing the appropriate PPE in accordance with the type of risk present in the workplace (characteristics of the PPE and category to which it belongs) to the employer (user). Therefore, it is advisable to verify the suitability of the characteristics of this model for your requirements before using it. The employer must also provide preliminary information to the worker concerning the risks which the PPE protects him/her from, ensuring, if necessary, adequate training on the correct and practical use of the PPE. These manufacturer's instructions for use must be kept for the entire duration of the PPE life span.

Certification body: Centro Tessile Cotoniero e abbigliamento S.p.A. Piazza Sant'Anna 2 21052 Busto Arsizio VA European notification number 0624
 PPE subjected to surveillance by the Notified Body itself.

Garment made with the following fabric
 weight 53g/sq. m. colour white

Category Regulation (EU) 2016/425): Illrd
 Size: S, M, L, XL, XXL

USE
 The garments covered by these manufacturer's instructions for use meet the specifications contained in the European standards and are suitable for the use indicated below; they are NOT suitable for any use not mentioned herein.

- | | |
|---------------------------------|---|
| Regulation (EU) 2016/425 | European regulation on personal protective equipment |
| UNI EN ISO 13688:2013 | General requirements for safety, ergonomics and sizes |
| UNI EN ISO 14126:2004 | Clothing for protection against biohazard Type PB6-B |
| EN 13034:2005+A1: 2009 | Protective clothing against liquid chemicals Type PB6-6B |
| EN 14605:2005+A1:2009 | Protective clothing against liquid chemicals Type PB-4B |

GENERAL WARNINGS

The garment offers partial protection of the body, therefore it must be integrated, according to the intended use, with suitable PPE for protecting the uncovered parts of the body (legs, hands, face, etc.). Protect the uncovered parts of the body with protective gloves, possible masks, etc.
 The indicated safety features are ensured only if the garments are of an adequate size, correctly worn, fastened and in perfect condition. Before each use, carry out a visual check to ensure that the devices are in perfect condition, intact; should the garments not be intact (e.g. unstitched, torn or punctured), they must be replaced.
 We decline all responsibility for any damage or consequence deriving from improper use, or should the devices have undergone modifications of any kind to the certified configuration. If the instructions in the manufacturer's instructions for use are not complied with, the PPE will lose its effectiveness.
 The user must not remove clothing while still in the hazardous work area.
 Flammable material, keep away from flames.

Physical Characteristics- UNI EN ISO 13688:2013		Requirements	Results
Fabric pH determination		3,5<pH<9,5	Pass
Tape pH determination		3,5<pH<9,5	6.6
Cuff pH determination		3,5<pH<9,5	6.4
Physical Characteristics- UNI EN 13034:2005 Type 6		Requirements	Results/Class/Conformity
Penetration by spray			Per partial body Not applicable

Non-woven Requirements- UNI EN 14325:2005											
Test	Requirements		Results	Test	Requirements		Results	Test	Requirements		Results
Abrasion resistance (UNI EN 530 met. 2)	Class 6	>2000 c.	Class 2	Tensile strength (EN ISO 13934-1)	Class 6	>1000 N	Class 2	Flexural strength (EN 7854)	Class 6	>100.000 c.	Class 6
	Class 5	>1500 c.			Class 5	>500 N			Class 5	>40.000 c.	
	Class 4	>1000 c.			Class 4	>250 N			Class 4	>15.000 c.	
	Class 3	>500 c.			Class 3	>100 N			Class 3	>5.000 c.	
	Class 2	>100 c.			Class 2	>60 N			Class 2	>2.500 c.	
	Class 1	>10 c.			Class 1	>30 N			Class 1	>1000 c.	
Test	Requirements	Results	Test	Requirements	Results	Test	Requirements	Results	Test	Requirements	Results
Trapezoidal tear resistance (EN ISO 9073-4)	Class 6	>150 N	Class 1	Puncture resistance (EN 863 - EN 13034)	Class 6	>250 N	Class 2	Ignition resistance and flammability (EN 13274-4 - EN 1073-2)	Not performed		
	Class 5	>100 N			Class 5	>150 N					
	Class 4	>60 N			Class 4	>100 N					
	Class 3	>40 N			Class 3	>50 N					
	Class 2	>20 N			Class 2	>10 N					
	Class 1	>10 N			Class 1	>5 N					

Biological Protection Characteristics – Resistance to penetration- UNI EN 14126:2004											
Test	Requirements		Results	Test	Requirements		Results				
Penetration of pathogens carried by blood and other body fluids: Phi-X174 bacteriophage method (ISO 16603/16604)	Class 6	20 kPa	Class 6	Wet bacterial penetration (ISO 22610) test on microorganisms: staphylococcus aureus	Class 6	min>75	Class 6				
	Class 5	14 kPa			Class 5	60 < min ≤ 75					
	Class 4	7 kPa			Class 4	45 < min ≤ 60					
	Class 3	3,5 kPa			Class 3	30 < min ≤ 45					
	Class 2	1,75 kPa			Class 2	15 < min ≤ 30					
	Class 1	0 kPa			Class 1	≤ 15 min					
Test	Requirements	Results	Test	Requirements	Results						
Penetration by contaminated biological liquid aerosols (ISO DIS 22611) - test on microorganisms: staphylococcus aureus	Class 3	log > 5	Class 3	Penetration of biologically contaminated dusts (EN ISO 22612) - test on microorganisms: Bacillus subtilis spores	Class 3	≤ 1					
	Class 2	3 < log ≤ 5			Class 2	1 < log ufc ≤ 2					
	Class 1	1 < log ≤ 3			Class 1	2 < log ufc ≤ 3					

Chemical characteristics – Permeation resistance- Penetration of liquids - UNI EN 13034:2009											
Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results
Sulphuric acid 30% (UNI EN 6530)	Class 3	< 1%	Sodium hydroxide 10% (UNI EN 6530)	Class 3	< 1%	O-Xilene (UNI EN 6530)	Class 3	< 1%	Butanol (UNI EN 6530)	Class 3	< 1%
	Class 2	< 5%		Class 2	< 5%		Class 2	< 5%		Class 2	< 5%
	Class 1	< 10%		Class 1	< 10%		Class 1	< 10%		Class 1	< 10%
		2.1 % Class 2			1.5 % Class 2			5.2 % Class 1		4.5 % Class 2	

Chemical characteristics – Permeation resistance- Liquid repellency - UNI EN 13034:2009											
Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results
Sulphuric acid 30% (UNI EN 6530)	Class 3	> 95 %	Sodium hydroxide 10% (UNI EN 6530)	Class 3	> 95 %	O-Xilene (UNI EN 6530)	Class 3	> 95 %	Butanol (UNI EN 6530)	Class 3	> 95 %
	Class 2	> 90 %		Class 2	> 90 %		Class 2	> 90 %		Class 2	> 90 %
	Class 1	> 80 %		Class 1	> 80 %		Class 1	> 80 %		Class 1	> 80 %
		97,9 % Class 3			98,5 % Class 3			94,8 % Class 2		95,5 % Class 3	

Chemical characteristics - Permeation of liquids -Non-woven - UNI EN 13034:2009						Chemical characteristics - Permeation of liquids -Seams - UNI EN 13034:2009					
Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results	Chemical substance	Requirements	Results
Sulphuric acid 30% (UNI EN 6530)	Class 6	>480 min	Sodium hydroxide 10% (UNI EN 6530)	Class 6	>480 min	O-Xilene (UNI EN 6530)	Class 6	>480 min	Butanol (UNI EN 6530)	Class 6	>480 min
	Class 5	>240 min		Class 5	>240 min		Class 5	>240 min		Class 5	>240 min
	Class 4	>120 min		Class 4	>120 min		Class 4	>120 min		Class 4	>120 min
	Class 3	>60 min		Class 3	>60 min		Class 3	>60 min		Class 3	>60 min
	Class 2	>30 min		Class 2	>30 min		Class 2	>30 min		Class 2	>30 min
	Class 1	>10 min		Class 1	>10 min		Class 1	>10 min		Class 1	>10 min
		>480 min Class 6			>480 min Class 6			>480 min Class 6		>480 min Class 6	

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Resistance to antiblastic and chemotherapeutic drugs- Non-woven - UNI EN 14605:2009											
Reagent	Requirements		Results	Reagent	Requirements		Results	Reagent	Requirements		Results
Cyclofosamide monohydrate (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Doxorubicin hydrochloride (Adriamycin) (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Methotrexate (UNI EN 6529)	Class 6	>480 min	>480 min Class 6
	Class 5	>240 min			Class 5	>240 min			Class 5	>240 min	
	Class 4	>120 min			Class 4	>120 min			Class 4	>120 min	
	Class 3	>60 min			Class 3	>60 min			Class 3	>60 min	
	Class 2	>30 min			Class 2	>30 min			Class 2	>30 min	
	Class 1	>10 min			Class 1	>10 min			Class 1	>10 min	
Vincristine sulphate salt (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Daunorubicin hydrochloride (UNI EN 6529)	Class 6	>480 min	>480 min Class 6		Class 6	>480 min	
	Class 5	>240 min			Class 5	>240 min			Class 5	>240 min	
	Class 4	>120 min			Class 4	>120 min			Class 4	>120 min	
	Class 3	>60 min			Class 3	>60 min			Class 3	>60 min	
	Class 2	>30 min			Class 2	>30 min			Class 2	>30 min	
	Class 1	>10 min			Class 1	>10 min			Class 1	>10 min	

Resistance to antiblastic and chemotherapeutic drugs- Seams - UNI EN 14605:2009											
Reagent	Requirements		Results	Reagent	Requirements		Results	Reagent	Requirements		Results
Cyclofosamide monohydrate (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Doxorubicin hydrochloride (Adriamycin) (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Methotrexate (UNI EN 6529)	Class 6	>480 min	>332 min Class 5
	Class 5	>240 min			Class 5	>240 min			Class 5	>240 min	
	Class 4	>120 min			Class 4	>120 min			Class 4	>120 min	
	Class 3	>60 min			Class 3	>60 min			Class 3	>60 min	
	Class 2	>30 min			Class 2	>30 min			Class 2	>30 min	
	Class 1	>10 min			Class 1	>10 min			Class 1	>10 min	
Vincristine sulphate salt (UNI EN 6529)	Class 6	>480 min	>480 min Class 6	Daunorubicin hydrochloride (UNI EN 6529)	Class 6	>480 min	>480 min Class 6		Class 6	>480 min	
	Class 5	>240 min			Class 5	>240 min			Class 5	>240 min	
	Class 4	>120 min			Class 4	>120 min			Class 4	>120 min	
	Class 3	>60 min			Class 3	>60 min			Class 3	>60 min	
	Class 2	>30 min			Class 2	>30 min			Class 2	>30 min	
	Class 1	>10 min			Class 1	>10 min			Class 1	>10 min	

SHELF LIFE

We suggest using the product within a period of five years from the date of manufacture written on the label.

TRANSPORT AND STORAGE

Transport and store the garment in its original packaging in a cool and dry place, not dusty, away from heat sources and from light. Be careful not to crease or crush.

DISPOSAL

If the garments have not been contaminated with particular substances or products, they can be disposed of as normal textile waste, otherwise follow the legal requirements in force for special waste.

EU DECLARATION OF CONFORMITY:

It is possible to access the EU Declaration of Conformity via the internet address: <https://deltamed.pro/prodotti/divisione-or/dpi-sanitari>

MAINTENANCE

We recommend carefully reading the symbols displayed on the label of each individual garment and strictly following these indications. Washing treatments that do not comply with what is reported on the label could alter the safety features of the garment. Cleaning, maintenance or disinfectant products must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions.

MARKING

<p>MANUFACTURER ①</p> <p>PRODUCT LINE ②</p> <p>MODEL ③</p> <p>CONFORMITY MARKING ④</p> <p>CHEMICAL HAZARD PICTOGRAM ⑤</p> <p>BIOLOGICAL HAZARD PICTOGRAM ⑥</p> <p>DISPOSABLE SYMBOL ⑦</p> <p>SIZE ACCORDING TO STANDARD EN ISO 13688:2013 ⑧</p> <p>SIZE ⑨</p> <p>USERS MUST READ THESE INSTRUCTIONS ⑩</p> <p>MANUFACTURER'S BATCH NUMBER ⑪</p> <p>MAINTENANCE PICTOGRAM: DO NOT WASH ⑫</p> <p>MAINTENANCE PICTOGRAM: DO NOT USE BLEACH ⑬</p> <p>MAINTENANCE PICTOGRAM: DO NOT IRON ⑭</p> <p>MAINTENANCE PICTOGRAM: DO NOT DRY CLEAN ⑮</p> <p>MAINTENANCE PICTOGRAM: DO NOT TUMBLE DRY ⑯</p> <p>PICTOGRAM: KEEP AWAY FROM FIRE ⑰</p>	
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BODY DIMENSIONS ACCORDING TO UNI EN ISO 13688:2013

Sizes in cm		S	M	L	XL	XXL
A	Height	156-164	164-175	172-180	180-188	188-196
B	Chest	90-94	94-98	98-102	106-110	114-118

MEANING OF THE MARKING: it is a guarantee of free movement in the trade of the products and goods within the European Union. The CE marking on the product means that the product meets the essential requirements set out in Regulation (EU) 2016/425.