

LINE **SHIELD Work<sup>®</sup>**  
INDIVIDUAL PROTECTION

MODEL **SAFELAB Gown**

PROTECTIVE CLOTHING CATEGORY III

PPE 3<sup>rd</sup> Category (REGULATION (UE) 2016/425)

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EU DECLARATION OF CONFORMITY: The EU Declaration of Conformity is available at the internet address: <https://deltamed.it/prodotti/divisione-or/dpi-sanitari>

Identification and description of the SHIELDWork® Individual Protection Line

Model: SAFFI AB GOWN

Gown reinforced in the front and the whole length of the sleeves with polypropylene-polyethylene material 63 g/m<sup>2</sup> (PPSB 38 g/m<sup>2</sup> + PE 25 g/m<sup>2</sup>); the back is made of polypropylene material (PPSB 38 g/m<sup>2</sup>). Gown back fastening, belts at the waist and Velcro at the neck. Gown with elastic at the wrists or with a cuff. Gown in blue colour. Sizes available: S - M - L - XL - XXL-XXXL Body measurements in cm (EN ISO 13688:2013)

Size in cm	S	M	L	XL	XXL	XXXL
A Height	156-164	164-172	172-180	180-188	188-196	196-204
B Chest	90-94	94-98	98-102	106-110	114-118	122-126

Fields of application:

SAFFI AB GOWN are designed for partial protection of the body against liquid chemical products, antiblastic and chemiotherapeutic drugs and infectious agents. Protective clothing particularly recommended for medical/pharmaceutical personnel assigned to manipulating cytostatic substances as well as service personnel assigned to cleaning and maintenance or transport and disposal operations.

Applied harmonised standards: EN ISO 6530:2005, EN 13034:2005 + A1:2009, EN ISO 13688:2013, EN 14126:2003, EN 14325:2004, EN 14605:2005 + A1:2009

Classification:

Gowns for partial protection of the body (front and sleeves) to be worn in the presence of the following chemical and biological hazards:

- Protective clothing against liquid chemicals (Type PB[4])
- Protective clothing against small splashes of liquid chemicals (Type PB[6])
- Protective clothing against infectious agents
- Protective clothing, resistant to contact with synthetic blood and body fluids
- Verification with Phi-X174 bacteriophage

Since the SAFFI AB GOWN is a PB partial protection garment it was not subjected to the spray test foreseen for clothing that completely protects the body. For areas of the body not covered by the garment, there must be provisions for suitable devices capable of guaranteeing at least the same level of protection, verifying their compatibility with this model. Exposure times to substances depend on the penetration characteristics of the agents and are shown in the tables included in these instructions.

Preparation for use: Take the garment from its individual package, put the gown on so that the opening is at the back, and position the Velcro fastening on your neck placing the male part over the female part, then knot the two belts at the waist. Lastly, after positioning the antiblastic gloves, make sure that the glove cuff is always worn over the gown sleeve, whether it is elastic or knit. If it is necessary to integrate body protection with other devices, such as gloves, respirators, footwear, etc., they must have at least the same chemical protection characteristics and verification must be made of their compatibility with the garment. Make sure that the combination of accessories is carried out correctly and is not a source of danger.

Warning: Device performance is guaranteed only on condition that the clothing is worn and fastened correctly, and a suitable size has been chosen.

Limitations of use: Indications and use not mentioned in this information note are intended as non-implementable. The user is the only person able to judge whether the device is really suitable and adequate for his/her own needs and to evaluate how long the device may be worn for performing a certain operation, taking into account the protective characteristics, comfort and exposure to heat. For further information about the protective characteristics, please contact the manufacturer.

The manufacturer is not responsible if SAFFI AB GOWN are used improperly or not following these instructions.

Cleaning: Disposable device. Not applicable

Disinfection: Disposable device. Not applicable

Revision: Disposable device. Not applicable

Maintenance: Disposable device. Not applicable

Preservation: The garment must be preserved in its original packaging and in an appropriate, dry place, away from sources of heat, direct light and UV rays.

Duration: It is recommended to use the garment within 5 years from the date of manufacture shown on the transport packaging label.

Disposal: SAFFI AB GOWN may be incinerated or buried in special controlled dumps, with no risk for the environment. Disposal of contaminated garments is disciplined by local or national laws.

Caution: Check visually that before use the device is whole (no holes, tears, cuts, etc.) and in perfect condition. Check that the size selected is suitable. If tears, rents and/or rips in seams occur during use, immediately leave the area of operations and replace the garment. Replace the garment after each intervention or at least after each work shift: the garment is good for single use only (disposable). Wearing chemical protective clothing may cause heat stress. This information note must always be available at the user company and kept as long as this type of PPE is in use.

The manufacturer declines responsibility for damage caused by improper use or use that is not relevant to these instructions. For further information, contact the manufacturer.

The model has been subjected to EC examination by the Notified Organism no. 0624 Centrocot – Centro Tessile Cottoniero e Abbigliamento S.p.A. – Piazza S. Anna, 2 – 21052 Busto Arsizio (VA). Centrocot is also an organism assigned for the annual check of category III<sup>A</sup> PPES.

Physical Characteristics

Properties	Product standard	Test standard	U/M	Value	Class
Abrasion resistance (Martindale)	UNI EN 14325:2005	UNI EN 530:2010 Met. 2 + UNI EN 14325:2005 Par. 4.4	Cycles	>2.000	6 of 6
Resistance to damage by flexion - MD	UNI EN 14325:2005	UNI EN ISO 7854:1999 Met. B + UNI EN 14325:2005 Par. 4	Cycles	100.000	6 of 6
Resistance to damage by flexion - XD	UNI EN 14325:2005	UNI EN ISO 7854:1999 Met. B + UNI EN 14325:2005 Par. 4	Cycles	100.000	6 of 6
Tear resistance - MD	UNI EN 14325:2005	UNI EN ISO 9073-4:1999 + UNI EN 14325:2005 Par. 4.7	N	50,6	3 of 6
Tear resistance - XD	UNI EN 14325:2005	UNI EN ISO 9073-4:1999 + UNI EN 14325:2005 Par. 4.7	N	30,2	2 of 6
Traction and lengthening resistance - MD	UNI EN 14325:2005	UNI EN ISO 13934-1:2013 + UNI EN 14325:2005 Par. 4.9	N	85	2 of 6
Traction and lengthening resistance - XD	UNI EN 14325:2005	UNI EN ISO 13934-1:2013 + UNI EN 14325:2005 Par. 4.9	N	59	1 of 6
Perforation resistance	UNI EN 14325:2005	UNI EN 863:1997 + UNI EN 14325:2005 Par. 4.10	N	10,2	2 of 6
Resistance of seams – grab method	UNI EN 14325:2005	UNI EN ISO 13935-2:2014 + UNI EN 14325:2005 Par. 5.5	N	56	2 of 6
Properties	Product standard	Test standard	Requirements	Value	
pH of the aqueous extract - Laminated non-woven fabric	UNI EN ISO 13688:2013	UNI EN ISO 3071:2020 + UNI EN ISO 13688:2013 Par. 4.2		3,5<pH<9.5	6.4
pH of the aqueous extract - Non-woven fabric	UNI EN ISO 13688:2013	UNI EN ISO 3071:2020 + UNI EN ISO 13688:2013 Par. 4.2		3,5<pH<9.5	9.0
pH of the aqueous extract -cuff	UNI EN ISO 13688:2013	UNI EN ISO 3071:2020 + UNI EN ISO 13688:2013 Par. 4.2		3,5<pH<9.5	6.1
Properties	Product standard	Test standard	U.M.	Value	
Aromatic amines derived from azo dyes	UNI EN ISO 13688:2013	UNI EN 14362-1:2017 + UNI EN ISO 13688:2013 Par. 4.2		mg/kg	< 1

Chemical characteristics – Permeation resistance

Chemical substance	Product standard	Test standard	U/M	Penetration index - Average value	Class
Sulphuric acid 30%	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	0.0	3 of 3
Sodium hydroxide 10%	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	0.0	3 of 3
O-Xilene	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	0.0	3 of 3
Butanol	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	0.0	3 of 3

Chemical substance	Product standard	Test standard	U/M	Repellency index- Average value	Class
Sulphuric acid 30%	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	98,9	3 of 3
Sodium hydroxide 10%	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	98,7	3 of 3
O-Xilene	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	97,9	3 of 3
Butanol	UNI EN 14325:2005	UNI EN ISO 6530:2005 + UNI EN 14325:2005 Par. 4.12 e 4.13	%	96,7	3 of 3

Resistance to antiblastic and chemiotherapeutic drugs

Reagent	Product standard	Test standard	U/M.	Time interval. (min.)	Class
Cyclofosamide monohydrate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Doxorubicin hydrochloride (Adriamycin)	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Methodretaxate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Fluorouracil	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Vincristine sulphate salt	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Daunorubicin hydrochloride	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6

N.B.: Permeation test carried out on gown material

Reagent	Product standard	Test standard	U/M.	Time interval. (min.)	Class
Cyclofosamide monohydrate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>367	5 of 6
Doxorubicin hydrochloride (Adriamycin)	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Methodretaxate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Fluorouracil	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>49	2 of 6
Vincristine sulphate salt	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>480	6 of 6
Daunorubicin hydrochloride	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>170	4 of 6

N.B.: Permeation test carried out on gown seams

Biological Protection Characteristics – Resistance to penetration

Properties	Product standard	Test standard	U/M	Value	Class
Blood and body fluid penetration. Synthetic blood method	UNI EN 14126:2004	ISO 16603:2004+ UNI EN 14126:2004 Par. 4.1.4.1	kPa	20	6 of 6
Penetration of pathogenic agents transmitted by flood and other body fluids. Bacteriophage (Phi-X174) method	UNI EN 14126:2004	ISO 16604:2004+ UNI EN 14126:2004 Par. 4.1.4.1	kPa	20	6 of 6
Bacterial penetration when damp	UNI EN 14126:2004	UNI EN ISO 22610:2006+ UNI EN 14126:2004 Par. 4.1.4.2	Min.	75	6 of 6
Penetration of biologically contaminated liquid aerosols	UNI EN 14126:2004	UNI EN ISO 22611:2003+ UNI EN 14126:2004 Par. 4.1.4.3	Log	>5	3 of 3
Penetration of biologically contaminated dusts	UNI EN 14126:2004	UNI EN ISO 22612:2005+ EC1-2011 + UNI EN 14126:2004 Par. 4.1.4.4	Log UFC	<1	3 of 3