INFORMATION NOTE

LINE SHIELDWork®

INDIVIDUAL PROTECTION

MODEL SURGICAL SAFE GOWN

PROTECTIVE CLOTHING CATEGORY III

PPE 3rd Category (REGULATION (UE) 2016/425)

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

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DELTA MED MEDICAL DEVICES
Solutions for Health

PART OF NUMANTEC HUMAN INNOVATION TECHNOLOGY

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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 *SHIELD*Work® IndividuaL Protection Line
Model: *SURGICAL SAFE GOWN*
Gown reinforced in the front and the whole length of the sleeves with polypropylene-polyethylene material 60 g/m2 (SMS 35 g/m2 + PE 25 g/m2); the back is made of polypropylene material (SMS 35 g/m2). Gown with surgical back fastening with n.4 belts at the waist and anticontagious holder, velcro closure at the neck and cotton/polyester jersey cuffs. Gown available in two versions: wrapped in medical paper with n. 2 dry-paper towels, or individually packed in polyethylene wrap, not wrapped in medical paper, without drypaper towels. Gown in blue colour.
Sizes available: S - M - L - XL - XXL 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: SURGICAL SAFE GOWN is disposable surgical gown for operating room to protect against infectious and chemical agents. Gown with the dual purpose of medical device (MD) and of the personal protective equipment (PPE). Clothing for partial body protection to be worn in the operating room during surgery or in controlled bacterial environment to protect the operator in the presence of liquid chemical products, cytotoxic and cytostatic drugs and infectious agents.
Applied harmonised standards: EN ISO 6530:2005, EN 13034:2005 + A1:2009, EN ISO 13688:2013, EN 13795:2013, EN 14126:2003 / AC:2004, 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 SURGICAL SAFE GOWN is a PB partial protection gown 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 gown, 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: Pick up the gown from the single case, if present remove the wrapping paper and use the wipes to dry user's hands and forearm. To grant aseptic dressing, the user must insert both hands firstly into sleeves openings, keeping the gown far from the body and subsequently hands and forearms into sleeves in order to firstly seal the neck with velcro strap and then posteriorly knotting the internal belts. The user, after putting gloves, assuring the cuff is put above the gowns wrist, must take anticontagious holder with both hands, separate the external belt from the holder, and with it twist on himself to reach the second belt, then separate it from the holder and tie up.
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 gown. 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 *SURGICAL SAFE 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 gown must be preserved in its original packaging and in an appropriate,
dry place, away from sources of heat, direct light and UV rays.
Duration: For the sterile device the shelf life is 5 years from the sterilization date with indication of expiration date (YYYY-MM) on the primary packaging. Do not use if the packaging is open or damaged. For the non sterile device is recommended to use the gown within 5 years from the date of manufacture shown on the transport packaging label.
Disposal: In compliance to the European Catalog Waste in accordance to the Committee decision 2000/532/EEC, the device itself can be considered as non hazardous waste which has not be disposed adopting particular precautions to avoid infections (disposal code 180104).
If contaminated with cytotoxic and cytostatic drugs it should be regarded as hazardous waste (disposal code 180108). Disposal of contaminated clothing it is governed 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 gown. Replace the gown after each intervention or at least after each work shift: the gown 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 Cotoniero 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^ PPES.
Physical Characteristics

Properties	Product standard	Test standard	U/M	Value	Class
Traction and lengthening resistance - MD	UNI EN 14605:2009	UNI EN ISO 13934-1:2013 + UNI EN 14325:2005	N	94.1	2 of 6
Traction and lengthening resistance - XD	UNI EN 14605:2009	UNI EN ISO 13934-1:2013 + UNI EN 14325:2005	N	55.9	1 of 6
Tear resistance - MD	UNI EN 14605:2009	UNI EN ISO 9073-4:1999 + UNI EN 14325:2005	N	44.0	3 of 6
Tear resistance - XD	UNI EN 14605:2009	UNI EN ISO 9073-4:1999 + UNI EN 14325:2005	N	17.0	1 of 6
Resistance of seams – grab method	UNI EN 14605:2009	UNI EN ISO 13935-2:2014	N	40,2	1 of 6
Resistance of seams – grab method	UNI EN 14605:2009	UNI EN ISO 13935-2:2014	N	38,2	1 of 6
Abrasion resistance (Martindale)	UNI EN 14605:2009	UNI EN 530:2010 + UNI EN 14325:2005	Cycles	1.000	4 of 6
Resistance to damage by flexion - MD	UNI EN 14605:2009	UNI EN ISO 7854:1999 Met.B + UNI EN 14325:2005	Cycles	100.000	6 of 6
Resistance to damage by flexion - XD	UNI EN 14605:2009	UNI EN ISO 7854:1999 Met.B + UNI EN 14325:2005	Cycles	100.000	6 of 6
Perforation resistance	UNI EN 14605:2009	UNI EN 863:1997 + UNI EN 14325:2005	N	8.48	1 of 6

Chemical characteristics – Permeation restistance

Chemical substance	Product standard	Test standard	U/M	Penetration index - Average value	Class
Sulphuric acid 30%	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	0.0	3 of 3
Sodium hydroxide 10%	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	0.0	3 of 3
O-Xilene	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	0.0	3 of 3
Butanol	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	0.0	3 of 3

Chemical substance	Product standard	Test standard	U/M	Repellency index Average value	Class
Sulphuric acid 30%	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	96.0	3 of 3
Sodium hydroxide 10%	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	96.5	3 of 3
O-Xilene	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	93.8	3 of 3
Butanol	UNI EN 13034:2009	UNI EN ISO 6530:2005 + UNI EN 14325:2005	%	93.1	3 of 3

Resistance to antiblastic and chemiotherapic drugs

Reagent	Product standard	Test standard	U/M.	Time interval. (min.)	Class
Cyclofosfamide monohydrate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>30	2 of 6
Doxorubicin hydrochloride (Adriamycin)	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Fluorouracil	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>30	2 of 6
Methotrexate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Vincristine sulphate salt	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Daunorubicin hydrochloride	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>30	2 of 6

N.B.: The permeation test was done on material body gown

Reagent	Product standard	Test standard	U/M	Time interval. (min.)	Class
Cyclofosfamide monohydrate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>30	2 of 6
Doxorubicin hydrochloride (Adriamycin)	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Fluorouracil	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>30	2 of 6
Methotrexate	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Vincristine sulphate salt	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>60	3 of 6
Daunorubicin hydrochloride	UNI EN 14605:2009	UNI EN 6529:2003 + UNI EN 14325:2005	min.	>10	1 of 6

N.B.: The permeation test was done on material seams gown

Biological Protection Characteristics – Resistance to penetration

Properties	Product standard	Test standard	U/M	Value
Blood and body fluid penetration. Synthetic blood method	UNI EN 14126:2004	ISO 16603:2004	kPa	20
Penetration of pathogenic agents transmitted by flood and other body fluids. Bacteriophage (Phi-X174) method	UNI EN 14126:2004	ISO 16604:2004	kPa	20
Bacterial penetration when damp	UNI EN 14126:2004	UNI EN ISO 22610:2006	minuti	75
Penetration of biologically contaminated liquid aerosols	UNI EN 14126:2004	ISO/DIS 22611:2003	Log10 UFC	>5
Penetration of biologically contaminated dusts	UNI EN 14126:2004	UNI EN ISO 22612:2005	Log10 UFC	<1