

Protection Devices

Camice GVS4 GVS4 Gown





Per la protezione da agenti infettivi e chimici (chemioterapici)

Descrizione

Camice di colore bianco, allacciatura posteriore, polsino in maglia Cuciture ad ultrasuoni e nastrate. Materiale accoppiato. Polipropilene nella parte interna con massa areica 40 gr/mq. Polietilene nella parte esterna con massa areica 25 gr/mq Prodotto monouso

Tempi di passaggio farmaci chemioterapici (disponibile elenco sostanze chimiche utilizzate) > 480 minuti

Materiale idrofobo, latex free.

Il prodotto non rilascia particelle (linting) Scadenza: 5 anni dalla data di produzione

Destinazione d'uso

Camice progettato per l'utilizzo in caso di esposizione ad agenti infettivi ed agenti chimici, inclusi i prodotti farmaceutici ad azione citostatica, nella preparazione di farmaci antiblastici,

nella somministrazione ed in caso di sversamento Può essere utilizzata anche in camere bianche ed ambiti sterili se sottoposto a trattamento di sterilizzazione.

Certificazioni

Il camice GVS4 è certificato quale DPI di III categoria ai sensi della Direttiva 89/686/CE (Recepimento del Decreto Legislativo 4 dicembre 1992 n. 475).

Norme tecniche applicate:

UNI EN14126/04 - UNI EN14605/09 - UNI EN 13034/09 - UNI EN ISO 13688/13

TAGLIE E CODICE / SIZES AND CODE

SFT00001	GVS4 Gown
SFT00001S	GVS4 Gown
SFT00001L	GVS4 Gown
SFT00001M	GVS4 Gown
SFT00001XL	GVS4 Gown





Protection Devices

Camice GVS4 GVS4 Gown





Gown with ultrasonic and taped seam. PPE in III category for the protection against infective agents and chemical/citotoxic drugs.

KIT B with GVS4 gown

GVS4 gown is patented protective clothing having excellent barrier properties, CE marked as Personal Protective Equipment (PPE) in category III for the protection against biological and chemical agents in accordance with requirement of EC Directive 89/686. Therefore, the gown is suitable to protect against biological agents in accordance with the requirement of the EC Directive 90/679 and to EC Directive 2000/54.

 ${
m GVS4}$ gown also protects against chemical agents with reference to EC Directive 98/24 and EC Directive

90/394 as acids, bases, disinfectants, cytotoxics in sanitary field.

PPE patented by CLcom: WO 04/043544A1

Technical features

GVS4 gown is made up by two different materials, polypropylene and polyethylene, assuring a

perfect wearing and comfort allowing normal movements, are physiologically innocuous and

hydrophobic. The PPE is latex free, produced with ultrasonic welding and taped seams, cuff and neck.

Application/areas of use

The operator can use GVS4 gown in working activities when there is exposure, or

potentially exposure,

to biological agents (bacteria, parasites, fungi, viruses as for example HBV, HCV, HIV, other agents responsible of Creutzfeldt-Jakob, BSE, Avian Flu) and to chemical agents (acid and bases) as well.

This gown is also suitable for the protection of the worker when preparing and administrating cytotoxic drugs.

GVS4 sterile version, grants protection to workers in operating room against biological and chemical agents.



Protection Devices

Camice GVS4 GVS4 Gown



Certification

GVS4 gown is patented protective clothing having excellent barrier properties, CE marked as Personal Protective Equipment (PPE) in category III for the protection against biological and chemical agents in accordance with requirement of EC Directive 686/89.

Protection against biological agents: verified by Notified Body in accordance with EN 14126/04 requirements and in accordance with American Society for Testing Materials ASTM F 1670/97 and F 1671/97 standards.

Protection against chemical agents: checked by Notified Body in accordance with harmonized standard EN 14605, EN 13034, EN340, concerning the tests using chemical agents.

The worker safety exposure to cytotoxics compositions has been verified by the Notified Body, using in the test provided by the above mentioned standard, some chemotherapic substances, generally used in hospital settings.

Materials (latex free & solvent free)

Polypropylene $40 \text{ g/m}^2 + \text{polyethylene } 25 \text{ g/m}^2$ Colors: White

Sterile

The PPE can be sterilized by ethylene oxide

Storage

The correct storage conditions are: room temperature from +5 °C to +40 °C; R.H. <60 % The PPE must be stored in a cool and dry place. They cannot stand the sunshine, fluorescent lights, x-rays and ozone and damp.

ultrasonic and taped seams

Knitted cuffs

Expire date

5 years from production date, following the above mentioned storage conditions in the original packaging.

Instruction for use

Please before use read the Instruction for use

Application limits

This clothing does not protect the operator against viral agents in group 4, with reference to the EC Directive 2000/54.

This garment does not protect against gas or areic. This clothing does not protect against heat/fire, cold, electricity (flammable stuff if getting in touch with fire or sources of heat) and against other kinds of risk not explicitly mentioned.

This clothing only protects the covered parts of the body and must be used together with others PPE protecting the uncovered parts of the body.

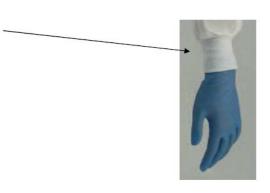
Utilization

In case of exposition to biological agents it must be used just once and it cannot be washed or

disinfected to used again. If the PPE has been contaminated by any kind of liquid and/or biological and chemical material, or a non visible contamination is supposed, change it.











Protection Devices

Camice GVS4 GVS4 Gown



TECHNICAL SPECIFICATIONS

(please read instruction for use for further information)

MEANINGFUL RESULTS CONCERNING THE BARRIER CHARACTERISTICS OF THE CLOTHING FOR THE PROTECTION TO BIOLOGICAL AGENTS (EN 14126/04)

Test pressure	0 Kpa	1.75 Kpa (0,25 psi)	3.50 Kpa (0,50 psi)	7.00 Kpa (1,00 psi)	14.00 Kpa (2.00 psi)
Sample 1	P	Р	P	P	P
Sample 2	Р	P	Р	P	P
Sample 3	P	P	P	P	P

MEANINGFUL RESULTS CONCERNING THE BARRIER CHARACTERISTICS OF THE CLOTHING FOR THE PROTECTION AGAINST CYTOTOXICS

Chemical product	Sample	Thickness (mm)	Passing through time (min)
Methotrexate	Average	0,27	> 480
5-Fluorouracil	Average	0,30	> 480
Vincristine Sulphate	Average	0,29	> 480
Daunorubicin Chlor- hydrate	Average	0,29	> 480
Doxorubicin Chlorhydrate	Average	0,29	> 480
Hidroxite Sodium Sulfuric acid (96%)	Average	0,29	> 480
,	Average	0,30	> 480
Cyclophosfamide	Average	0,27	> 480