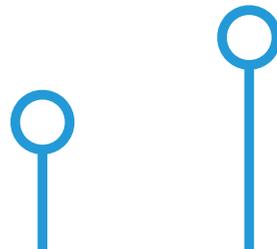




X-ONE

PONCHO

Grade A Disposable Protection



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The **X-ONE PONCHO** Grade A Disposable Protection has been designed to comply with the updated **Annex 1 GMP: Production of Sterile Medicines**. It is a **disposable GMP protective overdress** designed to cover the operator's body, arms, and hands with gloves and a helmet.



X-ONE PONCHO achieves a dual objective: **to prevent contamination of sterile environments** by operators and to ensure that **operators are not exposed** to the substances being processed.

The device offers **comfort and safety** for any type of operation. **X-ONE PONCHO** allows the operator to **wear it easily without contact** with its outer surface. The operator must first insert both hands, then put on the helmet,

and finally, without contaminating the outer surface thanks to the gloves, can unroll the gown covering the body up to the ankles.

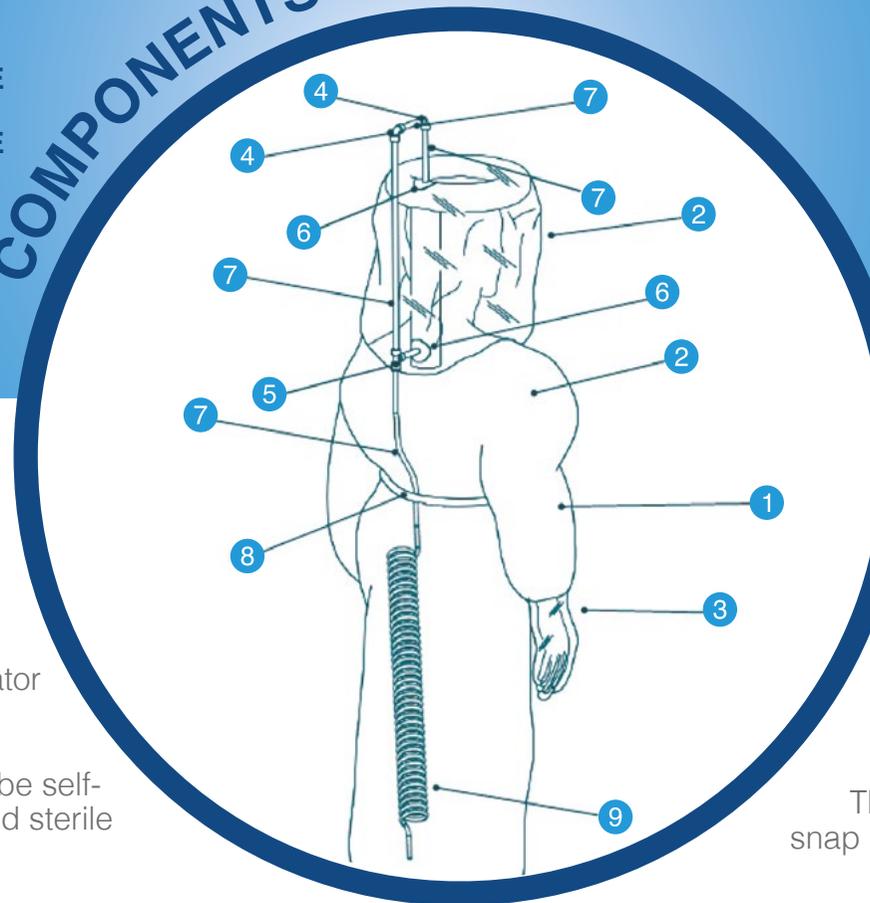
Like all our flexible products, it is produced in **ISO 8 and ISO 7** classified areas. **X-ONE PONCHO** comes in a **triple LDPE bag** closed by heat-sealing. The product is **gamma-irradiated**.



COMPONENTS

- 1 N.1 White Tyvek® 1422A PONCHO
- 2 N.1 Helmet in transparent antistatic LDPE
- 3 N.2 Gloves in transparent antistatic LDPE
- 4 N.2 Opaque white PP 90° curves
- 5 N.1 T-union in matt white PP

- 6 N.2 Barb in opaque white PP
- 7 Piping in transparent PU
- 8 N. 1 white silicone belt with N.2 stainless steel snap hooks
- 9 N.1 PU spiral



TECHNICAL SPECIFICATIONS

The PONCHO (1), heat-sealed to the helmet and made of Tyvek® 1422A, covers the operator up to the ankles.

The helmet (2) made of LDPE is designed to be self-supporting thanks to calibrated holes that feed sterile filtered air to assure:

- Correct vision.
- Correct breathing thanks to air injection.
- Agility in movements.
- No contamination of products.

The PONCHO sleeves end in two LDPE gloves (3), also heat-sealed. A transparent polyurethane piping system (7) and opaque white polypropylene fittings (4) (5) (6), placed on **X-ONE** PONCHOs' helmet, serve for conveying sterile filtered air necessary for breathing and support of the structure.

A very flexible polyurethane coil (9), connected via a quick coupling to the ventilation circuit, guarantees freedom of movement thanks to its extension up to 7 meters. Suggested air flow: 1,5 Bar - 80 L/min.



A silicone belt (8) secures the reaction circuit and the spiral to the **X-ONE** PONCHO.

This avoids damaging the coat, ensuring that the feed air escapes from the bottom. The belt is adjustable with two stainless steel snap hooks to be inserted into the multiple holes.

X-ONE PONCHO compliance

- The LDPE material of **X-ONE** PONCHO complies with:
- Reg. 1069/2009/EC and 142/2011/EC as well as the 'Explanatory Note EMEA/410/01, rev. 3' about BSE/TSE
 - EU Guideline EMA/CHMP/ICH/353369/2013)

Materials do not contain:

- Asbestos;
- Latex;
- Phthalates;
- Nitrosamines;
- Metal impurities;
- PVC;
- Raw materials of animal origins.





CSV life Science Group is a group of companies providing the pharmaceutical market with integrated solutions. Its final purpose is to successfully complete a project in all its phases: from strategic decisions to engineering activities definition, from process development and containment strategy up to the final validation.

The family has grown over the years and today consists of: CSV Life Science, CSV Construction, Pharma Hub, Officine Galesso, CSV Active and CSV Containment.

CSV Containment is the branch of the Group with strong expertise in containment systems for high potent API design, construction and integration.

The company can satisfy to the most demanding requirements thanks to its deep knowledge of the processes.



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