

INSTRUCTIONS – GLOVE FOR ISOLATOR MADE OF CSM (Y) 6/10mm MOUNTED ON SECURE CONNECTION RING (BCS)

Scope/Characteristics of the material and expiry

- This glove can be used in the domain of life sciences (medical/pharmaceutical industries).
- This glove is manufactured using CSM (chlorosulphonated polyethylene).
- This glove protects against certain chemical and mechanical risks, against radioactive contamination and provides protection against microorganisms and viruses.
- It can be used in an atmosphere containing ozone.
- This glove does not protect against ionising radiation.
- The shelf life of this glove in the original packaging stored under the conditions described below is 3 years.

Legislation, Risk analysis and recommendations for use

- This glove conforms to the regulation 2016/425.
- Please note, according to directive (UE) 89/656/CEE, the necessity to carry out a risk analysis relating to wearing the glove (e.g. breaking of leak tightness)
- Before each use, it is the responsibility of the user to check the quality and the integrity of the glove. The glove should be discarded if it has tears, holes or changes in surface appearance or colour that can show an alteration due to chemical products.
- For the assembly and disassembly of the gloves on the gloveboxes, please follow the instructions drafted by the safety manager and the glove port manufacturer.
- In case of a contamination, follow the instructions drafted by the safety manager.
- The gloves should be used at ambient temperature. Please contact the manufacturer for use under other temperature conditions.
- The gloves must be worn on clean and dry hands, with the nails cut short. Avoid wearing jewellery.
- In order to prevent possible risks of allergy and guarantee hand hygiene, it is recommended to wear disposable pre-gloves and to cover the forearm (long sleeves, cuffs, etc.)
- It is recommended to not wear gloves when there is a risk of being caught by moving machine parts.
- During the use of unspecified chemical products (those not mentioned in the list of chemical products), please contact the manufacturer for more information.
- This glove can only be mounted on a cuff equipped with the same device. The traction and integrity tests validated by IFTH have been conducted with an CSM (4/10 mm) glove and CSM (4/10 mm) cuff assembly. The choice of the cuff is made according to the risk analysis.
- Method of fastening between the glove and the cuff: The ring inseparable from the glove is assembled on the connected ring of the cuff by 3
 pads mounted on flexible arms. The 3 pads are clipped on to the 3 grooves in order to guarantee the fastening.
- Method of fastening between the cuff and the containment enclosure: The cuff is fixed on a glove box glove port.

Components:

• This glove does not contain substances in proportions in which they are known or suspected to have harmful effects on the user's health or hygiene under the foreseeable conditions of use.

Properties of the glove

- Protection against chemical products evaluated as per EN ISO 374-1+ A1 :2018
- Resistance to deterioration EN374-4:2013

| Tested products | | Level of permeation Palm | Average deterioration –palm (%) | Pictogram |
|-----------------|-----------------------|--------------------------------|---------------------------------------|-----------|
| Α | Methanol | 6 of 6 | 6.7 | 11 |
| М | Nitric acid 65% | 6 of 6 | -2.7 | ()(|
| P | Hydrogen peroxide 30% | 6 of 6 | -0.9 | AMP |

This information does not reflect the actual duration of protection at the workplace, or the differentiation between the mixtures and pure chemical products. The chemical resistance has been evaluated under laboratory conditions using the samples collected in the palm and the cuff and only concerns the tested chemical product. It can be different if it is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the place of work can differ from the typical test conditions, depending on the temperature, abrasion and deterioration. When they are worn, the protective gloves provide less resistance to hazardous chemical products owing to the change in their physical properties. Movements, tears, friction or deterioration caused by contact with chemical products, etc. can considerably reduce the actual duration of use. For corrosive chemical products, deterioration can be the most important factor to be taken into account in the selection of chemical-resistant gloves. Before use, it is recommended to inspect the gloves in order to ensure that they have no defects or imperfections.

| • | Protection agains | t viruses, | bacteria | and | moulds |
|---|--------------------|------------|-----------|-----|--------|
| | evaluated as per E | N ISO 37 | 4-5: 2016 | ; | |

• Leak-tightness evaluated as per EN374-2:2014

| Tests | Level | Pictogram |
|-------------------------------------------------------------------------------------|------------|-----------|
| Airtightness | Compliant | Q |
| Water-tightness | Compliant | (30) |
| Penetration by contaminated liquids under hydrostatic pressure (ISO 16604 method B) | No passage | VIRUS |

The resistance to penetration has been evaluated under laboratory conditions and only pertain to the tested test specimen.



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Protection against mechanical risks evaluated as per EN388+A1: 2018

| Tests | Level | Pictogram |
|-----------------------------------------|--------|------------|
| Abrasion | 3 of 4 | |
| Cut by slicing | X of 5 | ₹ ⊑ |
| Tear | 1 of 4 | (=) |
| Perforation | 1 of 4 | |
| Tests Section as per EN ISO 13997 :1999 | X | 3X11X |
| X: test not carried out | | |

Precision, Integrity, traction and ozone cracking

| Tests | Level |
|------------------------------------------------|-----------|
| Precision EN ISO 21420 + A1 :2024 | 5 of 5 |
| Integrity (pressure 30 mbar) EN421-2010 | Compliant |
| Traction EN421-2010 | Compliant |
| Ozone cracking resistance EN421-2010 | 4 of 4 |

The highest figures correspond to the highest performance levels.

Marking

Example of marking put on the glove and the packaging (see below)

PIERCAN SE XXXXXXXXXX LOGO PIERCAN E10330 Y 9 E6 2 BCS [XXXXX] (4) (5) (6) (7)(8)(9) (10) (11)

FR XXXXXX LOT : XXXX AAAA/MM (13)(12)



(14)

EN388+A1



(16)



EN ISO 374-1 + A1/ TYPE B

(17)



EN ISO 374-5 VIRUS

No.

Manufacturer – In charge of release to the market 2 QR code and Unique IDentifier "CE" marking and No. of the body in charge of the annual 3 inspection 4 Form 5 Length in mm 6 Material Size Thickness in 10th of mm 8 9 Diameter of rim in mm 10 Glove mounted on secure connection ring Product Item Code 11 Case number and batch number ("FR" French 12 manufacturing "US" American manufacturing) 13 Date of shelf life in storage + pictogram 14 "INFORMATION" pictogram "Protection against radioactive contamination" pictogram 15 EN 421-2010 "Protection against mechanical risks" pictogram 16 EN 388+A1:2018 "Protection against chemical risks" pictogram 17 EN ISO 374-1 +A1:2018 "Protection against micro-organisms and viruses" 18 pictogram EN ISO 374-5 :2016

DESCRIPTION

Sizes available in the main ambidextrous models

(15)

| REFERENCE | Ø RDG (glove port diameter) | SIZES |
|-----------|--------------------------------|--------------|
| E10330 | 110 | From 6 to 10 |



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Suitable packaging for transport

The gloves should be transported in their original packaging.

Storage

It is recommended to store gloves:

- In their original packaging, flat, black side of bag up and in their original box
- At a storage temperature between 5 to 35°C/41 to 95°F
- In a dry place away from direct light
- Away from electrical power source to prevent accelerated ageing.

> Cleaning and maintenance

- Gloves are not designed to be laundered.
- Prior to the use of unspecified chemicals, please contact the manufacturer for compatibility information.
- Do not contact gloves with sharp or pointed objects such as wire brushes, sandpaper, screwdrivers, or similar objects.
- If contaminated with chemicals, the gloves are for single use only

Treatment of the glove

- Non-recyclable glove
- It can be discarded as simple non-toxic waste if it is not soiled by a hazardous product
- If a glove is soiled, discard it through the appropriate channel

The EU Declaration of Conformity is available at: www.piercan.fr