Decontamination Sterilization

by **departicularization** and **Gamma irradiation**

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PIERCAN

Gloves and sleeves produced by dipping must be powdered with talcum powder for demolding. Depending on the finish required, gloves are either detackified or detackified and washed. In both cases, particles and fibers remain on these items.
This is why Piercan offers gloves and sleeves that are decontaminated by departicularization before being sterilized by Gamma irradiation. In some sectors, particular decontamination is sufficient, and sterilization is not necessary.

PHARMACEUTICAL INDUSTRY

LABORATORY / RESEARCH

HOSPITALS

NUCLEAR INDUSTRY

MICROELECTRONICS INDUSTRY

Decontamination & **Sterilization** Stages

Products receiving for treatment

↓

Dry decontamination cleaning – *Room ISO 6*

↓

Level class 200 – *Testing*

Granulometric analysis IEST-STD-CC-1246D

↓ *if conforming*

Packing – *ISO 6 room*

Certificate of conformity for particular decontamination
according to norm IEST-STD-CC-1246D (level class 200)

↓

Sterilization – *Method VD MAX 25*

Certificate of conformity for sterilization
according to norm ISO 11137-2

↓ *if conforming*

Decontaminated product delivred to Piercan

↓

Final Client

Certificate of conformity
for particular decontamination

Decontaminated and sterilized product delivred to Piercan

↓

Final Client

Certificate of conformity
for particular decontamination and sterilization

Dry Particular **Decontamination***

Our gloves and sleeves are departicularized by a dry process and packed in an ISO 6 class cleanroom. Cleaning is carried out on both the inside and outside of the glove, to obtain a 200 classification in accordance with IEST standard STD-CC-1246D. These products can therefore be used in a class 100 isolator.

CLEANING PROCEDURE

Dry decontamination is carried out on the inside and outside of each glove in an ISO 6 environment under flow with suction system. **Saving 17L of water per glove treated, dry particular decontamination is a more environmentally-friendly process.**

CONTROL LEVEL

A particle size analysis is carried out on a glove from the batch after cleaning, with particles and fibers removed by ultrasound.

The maximum number of particles per size corresponding to class 200 according to IEST-STD-CC-1246D is given in the table below.

Particle size	Maximum number of particles
> 15 µm	4180
> 25 µm	1230
> 50 µm	169
> 100 µm	16
> 200 µm	1

PACKING IN ISO 6 ROOM

Standard double packaging with easy opening under ISO 6 environment:

- 1st level classified 1000 type PE transparent with product label – Closure by thermosealing.
- 2nd level not classified transparent PE type – Heat seal closure.
- Identification label on 1st level bag.
- A Piercan certificate of conformity is routinely supplied with each order.

Gamma Ray **Sterilization***

In the case of sterilized products, after decontamination, the products are irradiated with Gamma radiation.

GAMMA RAY TREATMENT **PROCEDURE**

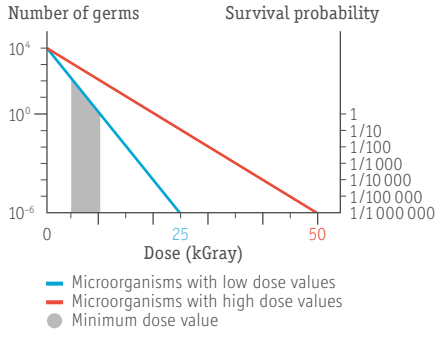
The process involves exposing the products to be treated to Gamma rays emitted by a Cobalt 60 source for a limited time. The photons emitted have energy levels too low to induce radioactivity.

OPERATING **PROCESS**

The sachets containing the products are packed in cartons placed on a pallet. The pallets are directly exposed to the Gamma radiation field, with a dose of between 25 and 50 kGray. Piercan has formalized a method for monitoring, labeling and tracing operations carried out both internally and externally.

A Piercan certificate of conformity is routinely supplied. An irradiation certificate is issued after routine inspection of the dosimeter.

Effects of ionizing radiation on micro-organisms



ADVANTAGES

- Gamma radiation has a high penetrating power for a relatively low dose rate.
- This sterilization method leaves no trace behind.
- The process has no residual effect and no temperature rise.
- Products are sterilized inside their packaging.
- Treatment is safe, reliable and reproducible.
- Radiosterilization is an environmentally-friendly alternative (no waste).

STERILIZATION **VALIDATION***

according to the VDmax 25 method and NF EN ISO 11137 and 11737 standards

Piercan has identified all the steps required to guarantee the sterility of products decontaminated and sterilized by Gamma irradiation, and demonstrated that the Gamma irradiation sterilization process used by the subcontracting company on the gloves is suitable.

*Subcontracted activity

Sales conditions

PIERCAN **PRODUCTS** CONCERNED

- Glove box gloves

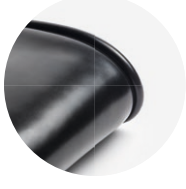
- Single ELS gloves or ELS gloves mounted on a standard ring or with BCS (Bague de Connexion Sécurisée) system

- Single sleeves or sleeves mounted on a standard ring or with BCS (Bague de Connexion Sécurisée) system to match the clip-on ELS gloves

PIERCAN **MATERIALS** CONCERNED

CHLORINATED NATURAL RUBBER

NEOPRENE

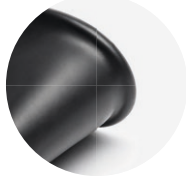


CSM

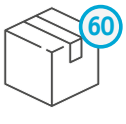
CSM/POLYURETHANE/CSM

POLYURETHANE/CSM

EPDM

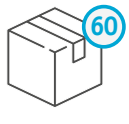


MINIMUM **ORDER QUANTITY**



GLOVE BOX GLOVES

ELS GLOVES



SLEEVES

ON **CUSTOMER REQUEST**

- Analysis of particle quantities after decontamination can be provided on request.
- Specific treatment to reduce endotoxin levels after sterilization. A glove endotoxin measurement report is available on request.

ANY QUESTIONS, NEED FURTHER INFORMATION?

Please do not hesitate to call us or write to us, Piercan is at your disposal for your projects!

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