



CTTM

## GAMMA IRRADIATION FOR STERILIZATION OF MEDICAL AND PHARMACEUTICAL SUPPLIES

### DESCRIPTION

**Radiation sterilization** is a well established and standardized method for sterilization of single use medical supplies and pharmaceutical products.

We are using Cobalt-60 gamma radiation in an industrial irradiator which can sterilize up to 10 m<sup>3</sup> of materials at the same time.

IRASM facility maintains a Quality Management System according to ISO 9001, ISO 13485, ISO 15378 and ISO 11137. The field of medical devices and pharmaceuticals is regulated by EU Directives (90/385/EEC, 93/42/EEC, 98/79/EC) and GMP (EudraLex - Volume 4).

### APPLICATION DOMAINS

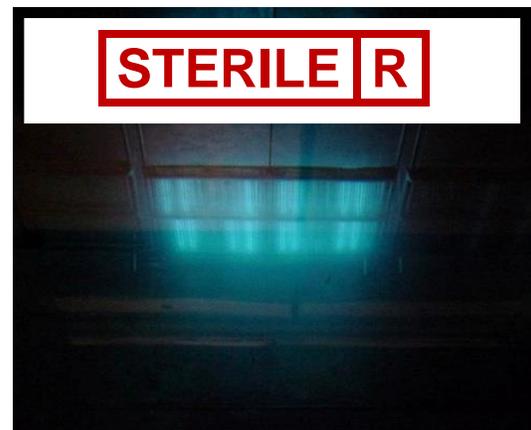
- Sterilization for single use medical devices (syringes, catheters, needles, cotton gauzes, dental implants, Petri dishes etc.)
- Sterilization for primary packaging materials and medicinal products (bottles, dispensers, gelatin capsules, sterile drugs, etc.)

### MAIN ADVANTAGES

One major advantage of radiation sterilization is the certainty of the biocide effect. The high energy photons have a high penetration in materials and allow the sterilization of in large volumes.

The biocide effect is given mainly by breaking the DNA double coil of living cells. These ensure the inactivation of any bioburden to the desired **Sterility Assurance Level**, according to the sterilization dose.

There is a clean process, with no chemical residues and few restriction on packaging materials



### CONTACT

[www.iasm.ro](http://www.iasm.ro)

tel: (021) 404 23 20

fax: (021) 457 53 31

**Ioan Valentin MOISE**

e-mail: [iasm@nipne.ro](mailto:iasm@nipne.ro)

**Ion Bogdan LUNGU**

e-mail: [ion.lungu@nipne.ro](mailto:ion.lungu@nipne.ro)

**Daniel Negut**

e-mail: [dnegut@nipne.ro](mailto:dnegut@nipne.ro)

### POTENTIAL CUSTOMERS OR COMMERCIAL APPLICATIONS

Medical devices and medicinal products manufacturers.

### KEYWORDS

**IRASM, Radiation processing, Gamma rays, Sterilization**