

RADIATION STERILIZATION VALIDATION

DESCRIPTION

The **IRASM Department** of NIPNE has the expertise and the potential to offer services on validation of sterilization by irradiation of health care products using the international standard EN ISO 11137 – Sterilization of health care products – Radiation:

-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices;

-Part 2: Establishing the sterilization dose;

-Part 3: Guidance on dosimetric aspects.

Sterilization validation ensures the **Sterility Assurance Level** of 10^{-6} , required by EU and Romanian regulations.

APPLICATION DOMAINS

Validation of sterilization by irradiation of health care products using one of the 3 methods for establishing the sterilization dose:

- **Method 1:** Dose setting using bioburden information;

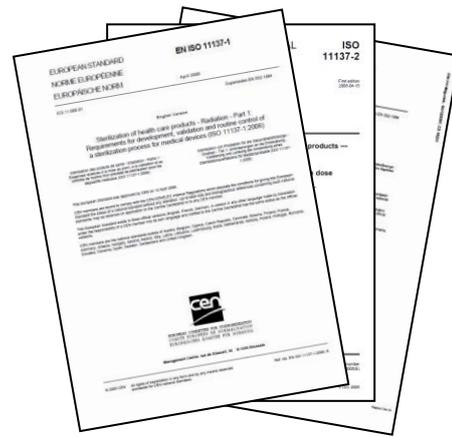
- **Method 2:** Dose setting using fraction positive information from incremental dosing to determine an extrapolation factor;

- **Method VD_{max}:** Substantiation of 15 kGy or 25 kGy.

MAIN ADVANTAGES

Irradiation of samples and microbiological tests are performed *in house*, in an integrated validation service. Microbiological tests are accredited according to ISO 17025.

The validation report covers all the requirements of ISO 11137.



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POTENTIAL CUSTOMERS OR COMMERCIAL APPLICATIONS

Local and foreign manufacturers of health care products.

KEYWORDS

IRASM, ionizing radiation, sterilization by irradiation, validation of sterilization, health care products

