GETINGE - LA CALHENE
LINAC TECHNOLOGIES DEPARTMENT
ELECTRON BEAM SPECIALISTS

Always with you
**ELECTRON BEAM SOLUTIONS DEDICATED TO YOU**

**GETINGE LINAC** is one of the world’s leading providers of e-beam systems. Our units are utilized for sterilization and radiography, and are well on their way to becoming the industry standard for all of the applications we are involved with. Our customers include most of the major players in their respective fields.

Our focus enables us to respond swiftly to provide the right solution for a given application. But we also have the advantage of being part of the Getinge Group, which is well known in the hospital and pharmaceutical industries.

We benefit from the isolator and transfer systems expertise provided by GETINGE LA CALHENE, our direct owner, which owns full service factories in France and the United States. We are the unique in providing you with expertise in both e-beam and isolator systems.

Based in Sweden and employing over 12,000 people worldwide, the Getinge Group comprises three business areas: Infection Control (under the Getinge brand, including Getinge Linac), Medical Systems (under the Maquet brand) and Extended Care (under the ArjoHuntleigh brand).

As part of the Getinge Group, Getinge Linac benefits from the resources of a multi-national corporation in terms of capital, administration, quality, management and research, as well as sales and service capacity. This enables us to dedicate our efforts to delivering outstanding electron beam solutions to you.

The Getinge Linac offices and workshop are based in Villebon sur Yvette, near Paris.
GETINGE LINAC designs, manufactures, installs and services sterilization and radiography systems utilizing electron beam linear accelerators. These industrial machines produce electron beams with different power and energy levels according to the relevant application:

- **Sterile transfer**, particularly in pharmaceutical applications.
- **Terminal sterilization** of medical and pharmaceutical products, for production lines and service centers (contract sterilization).
- **Industrial radiography** for security, non-destructive testing and other applications.
- **Research**, including food research.

Our primary product lines are **in-line sterilization systems** using electron beam. The electron beam provides the minimum irradiation dose of 25 kGy, which is the recognized standard for achieving a 6 log reduction (the required bioburden decrease).

These stand-alone systems are supplied with all ancillary equipment, i.e. shielding, conveyor, cooling, power, controls, automation, safety, ventilation and dosimetry systems. They can be fully interfaced with other elements of the production line, and all irradiation treatment parameters are recorded to ensure that cGMP requirements are fulfilled.
A COMPLETE RANGE OF DEDICATED PRODUCTS

• The SterStar™ in-line electron beam surface sterilization tunnel uses 3 KeVAC low-energy accelerators, each producing a 200 keV energy beam, to sterilize the product surface only, with no irradiation inside the product.

• The SterBox™ in-line electron beam sterilization tunnel uses 1 or 2 MeVAC medium-energy accelerators, each producing a 3 MeV, 4 MeV or 5 MeV energy beam. This unit provides complete sterilization of products inserted into a Class A environment, and/or terminal sterilization of single-use medical devices or pharmaceutical products. Beam energy and materials handling systems are customized for the product to be sterilized.

• The SterRoom™ e-beam sterilization system contains one or two high-energy high power CIRCE accelerators with a 10 MeV 20 kW beam. This high throughput system is suitable for production plants or service centers.

• The LINAX™ x-ray generator is an OEM product with a 4 MeV to 10 MeV accelerator. It is used by integrators for imaging of trucks and containers, and testing of large industrial parts.
Getinge Linac led the development of an in-line electron beam system, the SterStar, for decontamination of tubs containing pre-sterilized syringes entering a filling line contained within an isolator. With over 17 systems installed in Europe and the Americas, Getinge Linac has full knowledge of this sterile transfer application, giving the experience that can be applied to new projects. As a 100 % subsidiary of Getinge-La Calhène, Getinge Linac is the only supplier with expertise in both electron beam and isolation technology.

**SterStar**

**IN-LINE E-BEAM SURFACE STERILIZATION TUNNEL**

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**Product Features**
- Three electron beams with up to 200 keV energy and up to 3.5 mA electric current each (the beams are scanned over the product)
- Integrated inside an isolator loop which controls air circulation
- The product is fed by automated conveyor belt from the non-sterile entry area through the e-beam tunnel and delivered into the sterile area
- Modular “plug and play” equipment
- Process control system dialogues with filling machine and isolator upstream and downstream

**Advantages**
- In-line treatment at ambient temperature
- Continuous process (not batch)
- Easy to validate
- Complete integration with rest of line
- No residue, no recontamination
- Low energy electrons for surface decontamination only
Getinge Linac has developed the SterBox, an in-line sterilization tunnel using high energy electron beam for complete sterilization of products entering a Class A environment, and/or terminal sterilization of pre-packed medical devices or pharmaceutical products. The technology is well proven – SterBox systems are already being used in commercial production facilities. The stand-alone unit is designed to house a high energy electron beam accelerator, a customized handling system and all the necessary ancillary equipment within a compact area. It is a fast, continuous, room temperature sterilization unit.

**Product Features**
- No residue, no recontamination
- One electron beam accelerator with up to 5 MeV energy and up to 6 kW beam power
- Customized handling system adapted to product shape
- Lead shielding for operator protection
- Easy access for cleaning and maintenance
- Process control system dialogues with the production line upstream and downstream

**Advantages**
- Complete sterilization
- In-line treatment at ambient temperature
- Continuous process (not batch)
- Economical and rapid sterilization
- Easy to validate
- Complete integration with rest of line
- No residue, no recontamination

We also offer a Dual SterBox version with two electron beam accelerators for complete sterilization of larger items.
SterRoom
IN-HOUSE E-BEAM STERILIZATION UNIT

CIRCE high-energy electron beam accelerators are incorporated into SterRoom units, which can be located in-house to provide rapid, continuous sterilization of large volumes of products – right on your own premises. The in-house location can save you time and money, while giving you better control over the sterilization process.

Product Features
- Core sterilization.
- Fast continuous process.
- SterRoom sterilization unit for turnkey sterilization facility containing one CIRCE accelerator or two CIRCE accelerators facing each other for double penetration.
- Electron beam accelerator with up to 10 MeV energy and up to 20 kW beam power.
- Customized handling system.

Radiation Sterilization with an Off Switch

Configuration / Options
- The CIRCE II accelerator is available with 10 MeV beam energy and up to 20 kW power. This machine can treat various products requiring different irradiation doses, by adjustment of the conveyor speed which determines the exposure time of the product to the electron beam.
- The CIRCE III accelerator is available with adjustable energies (5 MeV, 7.5 MeV and 10 MeV) and 10 kW power. The flexibility of this machine makes it particularly suitable for research centers and pilot plants.
- Can also be located at Service Centers.
LINAX
X-RAY GENERATORS

The Linax X-ray generators offer a variety of mobile or fixed industrial radiography solutions such as non-destructive testing of large parts and discriminating scanning. The Linax is designed for optimal serviceability and operator ergonomics, and the system can operate indoors or outdoors under extreme climatic conditions. The Linax produces collimated X-ray beams from an electron beam with 0.2 mA average current and energies ranging from 3.5 to 10 MeV. The Linax delivers a typical dose rate of 150 mGy/min at 1 m from the X-ray source.

**Performances**
Energy: 3.5 – 10 MeV
Electron beam average current: 0.2 mA
E-BEAM SERVICE SOLUTIONS

Getinge Linac is known throughout the world for its know-how in the field of e-beam sterilization tunnels. We work together with our customers throughout the process of defining, designing, fabricating, validating and installing the e-beam machine, and we continue to provide assistance with the long-term use of the units.

SERVICES

Feasibility Studies
We can help develop product applications through initial product feasibility studies on a small scale in our facility. The goal is to find the most efficient and effective method of treating a given product configuration with an electron beam.

Customer Support Service
Our after-sales departments located in France and the United States service electron beam systems via maintenance contracts, service calls, visits, a “hot line” for technical assistance and supply of spare parts, many of which are available from stock. All of our products are delivered with a minimum 12-month guarantee.

Validation
Our engineers assist you in preparing and carrying out the validation and revalidation processes. Full documentation is available for the IQ, OQ and PQ steps.

Training
We provide comprehensive training programs for your staff. Theoretical and hands-on training modules are available for different staff levels.

QUALITY ASSURANCE

Getinge Linac is integrated in the Getinge La Calhène quality system and uses a Quality Management System conforming with the ISO 9001:2000 standard. The system is maintained and constantly updated in order to ensure and improve the quality of our products and work, and to improve client satisfaction by meeting all your requirements.
COMPLETE SOLUTIONS FOR CONTAMINATION PREVENTION

Getinge is the world’s leading provider of solutions for effective cleaning, disinfection and sterilization in the healthcare and life science sectors. We are dedicated to helping our customers provide maximum productivity in the most cost-efficient way. We do this by offering well thought through and customized solutions. This means that we are with our customers all the way from architectural planning and education to traceability and support – with complete solutions, long-term commitment and global presence. Getinge – Always with you.

GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. ArjoHuntleigh focuses on patient mobility and wound management solutions. GETINGE provides solutions for infection control within healthcare and contamination prevention within life sciences. MAQUET specializes in solutions, therapies and products for surgical interventions and intensive care.