

In General:

These General Terms and Conditions apply to all customers of IONMED ESTERILIZACIÓN, S.A.U. (hereinafter IONISOS IBERICA) unless expressly agreed to otherwise in writing. In the case where there is a signed Service Agreement/Contract which modifies these terms and conditions, then the said Agreement prevails.

Apart from a written communication indicating the contrary, IONISOS IBERICA will assume that these General Conditions have been accepted for all Electron Beam Treatment Orders sent.

Prices:

Our prices are without VAT unless expressly stated otherwise.

Payment of treatments should be made 30 days from the date that the invoice is issued, by bank transfer to the bank account indicated on the invoice. Any other form of payment should be agreed upon directly with the Commercial Dept. of IONISOS IBERICA and shall take into account the Law 15/2010 of July 5th, which establishes measures to combat late payment in commercial transactions.

Irradiation Orders:

An Electron Beam Treatment Order shall be correctly completed in full for each shipment. Communication of a shipment shall be made at least three days before the said shipment.

All Treatment Orders shall be confirmed by IONISOS IBERICA via e-mail indicating the date that the product will be available for collection. The normal turnaround time should be 5 working days (from date received), but this is not binding. In the case of a delay in respect to the confirmed date, IONISOS IBERICA must advise the customer. IONISOS IBERICA will not be held liable to pay in the case of delays unless expressly agreed to otherwise in writing.

IONISOS IBERICA reserves the right to not accept the order or initiate the treatment, until all the aspects necessary for the proper irradiation are clear.

Shipments shall be made in accordance with the planning indicated on the Electron Beam Treatment Order. The WAREHOUSE timetable being: Monday to Thursday 07:00h to 17:00h and on Fridays 07:00h to 15:00h.

Any type of special manipulation of the product must be requested in writing along with the Electron Beam Treatment Order. The cost of these special manipulations shall be invoiced separately from the treatment costs.

Shipment requirements:

Shipments should be sent on shrink wrapped pallets.

The merchandise shall be prepared in accordance to the dimensions, weight and material composition of each

product as they have been validated (see "Information on Performance Qualification").

Products that correspond to different treatments should be placed on distinct pallets. If this placement is not possible, then the contents of each pallet must be identified (e.g. by providing a packing list or by labeling each pallet with pallet notes).

IONISOS IBERICA shall not be held responsible for product that has not been packaged materials that are compatible with radiation, which may result in the deterioration of the product.

IONISOS IBERICA will not be held responsible for damages if the content received is different from that indicated on the Treatment Order, or from the documentation accompanying the material received.

Security Conditions:

The products to be treated will be neither explosive nor flammable. If they are toxic or dangerous, the Customer will supply beforehand all information and related documentation, where it exists, to ensure the safety of the handling operations.

Only the flammable liquids respecting the qualitative limits below are accepted at the installation for treatment at a dose inferior to 10 kGy MIN:

- $T_{\text{flash-point}} > 55^{\circ}\text{C}$
- volumetric alcoholometric Title < 40 %

In the event of a dangerous product (Pharmaceutical product, strong concentration or other), please attach with your first order the safety data sheet related to your product.

Responsibilities:

The Customer remains solely responsible, including against third parties, for the adequacy of the dose of treatment requested and the objectives pursued. It is the responsibility of the Customer to undertake the necessary tests (bioburden, materials resistance ...) to determine the dose required.

The Customer is the sole judge of the capacity of their product to withstand the treatment dose requested from IONISOS IBERICA. Any chemical or physical deterioration will have been determined via the Performance Qualification. If any change has been made, then it is the responsibility of the customer to inform IONISOS IBERICA of this change. Any such change may require product requalification.

The Customer is responsible for demonstrating evidence of product treatment to its own customers and regulation authorities. The Customer is responsible for the realization of the Performance

Qualification for the radiation treatment of its products.

IONISOS IBERICA ensures that treated products will receive the minimum dose required, not sterility. In the event of a breach of the requirements contained in these Conditions, IONISOS IBERICA cannot guarantee that the treated products will receive the requested dose.

Product Availability & Transport:

The date communicated via the Treatment Order confirmation should be the date that the products are collected, unless there is a subsequent communication made by IONISOS IBERICA. IONISOS IBERICA shall not be held responsible for any attempt to collect the product earlier than the date confirmed.

The transport making the collection must always identify itself with a collection order or with sufficient information to allow the release of the goods into their care.

In general the Customer should organize the transport. In the case where IONISOS IBERICA is requested to organize transport, IONISOS IBERICA reserves the right to select the transport company.

IONISOS IBERICA shall not be held responsible for product damaged during transportation, this applies to both transport organized by the customer and by IONISOS IBERICA.

Exact delivery times cannot be assured by IONISOS IBERICA and therefore cannot be held responsible for any delay once the product has left the premises.

IONISOS IBERICA cannot be held responsible for the damage or deterioration of the goods held at the installation for more than two days from the confirmed date of collection, unless a warehousing agreement exists with the customer.

Information on Performance Qualification:

This qualification consists of the placement of radiochromic dosimeters inside a box of product to determine the dose distribution inside. With this data treatment parameters to be used during production are calculated. This test is performed only once, provided that the size, weight and product distribution does not vary.

Products that have been sent for the Product Performance Qualification (dosimetric dose map) shall not be returned to the customer, and will be destroyed by IONISOS IBERICA.

Performance Qualification is required for medical devices, pharmaceuticals and veterinary products. IONISOS IBERICA recommended its implementation for all products, whether or not medical devices and the like.

Food:

In the case of products intended for human consumption, according to RD REAL DECRETO 348/2001 in Spain only dried herbs, spices and vegetable seasonings may be treated. For these there is an established maximum value of the overall dose of radiation absorbed of 10 kGy (kiloGray). To ensure compliance, these products can be sampled and analyzed at any time, so traceability must be preserved.

For products intended for export outside the EU, the legislation of the country of destiny will be enforced. IONISOS IBERICA, in compliance with the current legislation, will report to the competent authority information about any treatments made on food.

The maximum qualified surface density for any product sent to IONISOS IBERICA within the food sector is 8.5 g/cm².

Higher densities prevent treatment of the product. IONISOS is exempt from the costs derived from the return and/or repackaging of goods.

This parameter is calculated by dividing the weight of the bags in grams by the length and the width of the bag in centimeters:

$$\text{Density} = \text{weight (grams)} / (\text{width} \times \text{length}) \text{ (cm)}$$

$$\text{units} = \text{g/cm}^2$$

Customer Service and Complaints:

Communication of formal complaints must be received in writing via e-mail. Complaints should be lodged, whenever possible, within 5 days of collection of the goods from the IONISOS IBERICA installation.

IONISOS IBERICA is obligated to investigate and respond to a complaint in writing as soon as possible after receiving the complaint.

IONISOS IBERICA shall always seek to find a resolution acceptable to both parties. In the case where possible, the Customer must allow IONISOS IBERICA the opportunity to correct any deficiency.

Products affected by a Non Conformity that have been rejected, shall remain warehoused in IONISOS IBERICA at the disposal of the customer for a period of 6 months, unless otherwise stated. After this time the product shall be destroyed. IONISOS IBERICA is not liable for the cost of product affected by a No Conformity unless expressly agreed to otherwise in writing.

For any doubts, you are welcome to contact the Customer Service Dept. by telephone on: 34 969 32 72 55 or by E-mail: pedidos@ionisos.es (Timetable: Monday to Thursday from 8:30h to 14:00h and from 15:30h to 18:00h & Fridays from 8:30 h to 14:00 h).