

## TREATMENT ORDER FOR ELECTRON BEAM PERFORMANCE QUALIFICATION & TESTS

(Ionmed Esterilización S.A.U) Pol. Ind. Tarancón Sur – C/ Rocinante, 50 -16400 Tarancón (Cuenca) Telf. 969 32 04 96 - info@ionisos.es -www.ionisos.com

Customer Order N. o:		N.º ST (IONISOS):
(This number will appear on the associated in	voice)	

(This number will appear on the associated invoice)

Please,	complete th	e vellow	fields and	send it	back to	us by	e-mail:

	Company name			
	Company Tax No			
	Address			
CUSTOMER	Town & P.C.			
	Contact person			
(to invoice)	Telephone			
	E-mail (sending the invoices)			
	E-mail (sending documentation)			
	Documentation	Spanish	English	

	Medical Device	Notified Body No			
	Human Food	Indicate RGSEAA registration number			
TYPE OF PRODUCT	Primary packaging	Industrial			Animal Food
(mark "X" in the box	Food Packaging	Cosmetics			OTHER
	Medicines*	Are considered Medicines (human and veterinarian) active substances, exci and finished products			n) active substances, excipie

<sup>(\*)</sup> Please attach the safety sheet

PRODUCT IDENTIFICATION: Please fill in the following table with all the information you wish to include in the certificates. In case the products are used for the Performance Qualification, the REFERENCE and DESCRIPTION indicated will have to be the same as the one that you will use to identify the products in future deliveries or routine productions. If you consider that there are some legal requirements applicable to your product that we should know, please identify these requirements in the field OBSERVATIONS.

REFERENCE:	В		ватсн:		
DESCRIPTION:				•	
	(L x A x H) cm	Weight (	grams)	Noof Boxes/Samples	Dose (kGy)
DACKACING.					
PACKAGING:					
	Minimum Dose: Applicable to Dose Map exercises (Performance Qualification)				
TYPE OF DOSE (mark "X" in the box):  Mean Dose: Applicable to Human Food and po			wders.		
(mark x m the box):	Surface Dose: Applicable only to compatibility test of the product with the irradiation				
OBSERVATIONS:					

Please indicate the palletization with which we would receive the product in routine production:

PALLETIZING	Pallet 120 x 80 cm	Pallet 120 x 100 cm	
APPROVED	Nº boxes/layer pallet	Nº layers/pallet	

TEST TO PERFORM (mark "X" in the box):						
	1 Dose Map					
	3 runs of the Dose Map according to NCF / ISO 11137					
	Irradiation of samples to evaluate the effect at the maximum dose					
TYPE OF TEST	Irradiation of samples to Justify / Check the <b>Sterilizing Dose</b>					
	Compatibility of the product with irradiation at a surface dose					
	Dose verification dossier / Periodic Dose Checks and Determination of Bioburden					
	Other tests (Indicated in Observations of the request)					

DATES	Delivery date to IONISOS	<b>OBSERVATIONS:</b> If the product requires special security conditions for its handling or storage, please indicate it here:
	Required end date (if applicable)	

**Customer Signature & Date:** 



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A treatment order must be submitted for each type of test you want to perform.

Orders will be completely filled out. With this documentation the corresponding reports and certificates of the process will be edited. Subsequent changes in the documentation will imply an economic cost

The <u>documentation</u> can be edited in English or Spanish: there is a box on the application to indicate it. If NOTHING is indicated, it will be edited in Spanish.

Palletizing with Homologated pallet: if you still do not know it, please let us know before the first production.

Labels: During the production process, unless we are instructed otherwise, we will place 1 label per box / bag.



IONISOS does not send or manage the transport of the samples. Please organize it with your usual transport agency.

If the product requires special conditions for handling, please indicate it in Comments.

If you send us a box to make a dose map, this box must be identical to the one that we will later receive in routine productions:

Dimensions, weight, number of units / box, distribution and placement of the product inside.

It is the customer's responsibility to maintain the <u>qualification of the product</u>. Any subsequent change must be communicated to IONISOS to evaluate its impact, distribution and placement of the product inside.

Dose mapping is a <u>destructive test</u>. Please manage your collection and remember that the product used will not be suitable for later use.

For the treatment of <u>powdered product</u>, the surface density must be less than 8g / cm2. This parameter is calculated by dividing the weight of the bags by the length x width of the bag.

If the test that you are going to carry out is for production, send a representative bag of your production and verify beforehand that the density is less than 8g / cm2, if it is for tests, send your product in bags / sacks in such a way that the product lay as flat as possible.

Surface Density = Weight (grams) / (width x length) (cm)

units = g/cm2







argo (cm)

Ancho (cm)

No tener en cuenta esta parte para medir el largo del saco

For the irradiation of samples to justify or verify the sterilizing dose, the product must arrive to us perfectly identified, in monolayer, as flat as possible and in triple bag.

IONISOS is not responsible for possible negative results associated with inappropriate packaging.



For the irradiation of samples at a <u>superficial dose</u>, the product must reach us perfectly identified, in monolayer and as flat as possible, so that the radiation can easily pass through the product and the dose is as homogeneous as possible.