STERIS

Gamma Dose Specification Authorization

Customer Name:					
Minimum Specified Dose:		kGy	Maximum Specified Dose:		kGy

1.0 Reason for Change: ☐ Addition of New Product ☐ Change to Existing Dose Range

☐ Removal of Product Code ☐ Other (Please Specify): _____

2.0 Product Information:

If customer supplied document* will be used to provide dose and product codes, indicate the customer supplied document information in the space provided.

***Name of Customer Supplied Document:** _____ (attach signed/dated document to this form)

Product Code	Description

-Product codes must match customer label & customer packing list. If special post processing code is applicable, please indicate code in brackets.
Note: The description may include proper name, registration name, generic description, and/or product weight and dimensions.

☐ **Check here if any of the above product codes are mixed density material.**

☐ **N/A**

3.0 Product Classification:

☐ Finished Medical Device ☐ Generic Drug ☐ Human Drug/API ☐ Animal Drug ☐ Animal Food/Human Food

☐ Human Tissue Product **(Form 10 Required)** ☐ Human Blood Product **(Form 11 Required)** ☐ Food Packaging ☐ Labware ☐ Food/Spice

☐ Botanicals ☐ Cosmetics ☐ Other (Specify): _____

☐ **Check here if any of the above listed codes is an implantable medical device.**

4.0 Product Safety Information:

☐ **Check here if any of the above listed codes contain hazardous, flammable, corrosive, explosive, combustible, bio hazardous, or bio active materials.** (If checked, STERIS management: Contact the Senior Radiation Safety Manager)

☐ **Check here if any of the above listed codes are harmful, in anyway, to humans.** (If checked, MSDS must be provided before processing)

☐ **N/A**

5.0 Process Interruption (Ref 11137-1:2006):

☐ **N/A**

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☐ **Check here if your product will support microbial growth during an interruption of the irradiation process?**

If checked, must provide special handling instructions related to process interruption:

_____

6.0 Storage Conditions

STERIS AST facilities do not provide special environmental conditions unless arranged with STERIS prior to accepting product.

☐ **N/A**

☐ **Check here if any of the above listed codes contain environmental controlled requirements and list details below or in an attached document:**

_____

Customer Authorization:

Print Name: _____ **Title:** _____

Signature: _____ **Date:** _____

Note: Electronic signatures are not acceptable unless compliance to Part 11 can be demonstrated. Form can be completed electronically, and printed and signed in ink.

STERIS Approval:

Production Signature: _____ **Date:** _____

QS/RC Signature: _____ **Date:** _____