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 Code / Description	Product Code / Description

-Product codes must match customer label & customer packing list. If special post processing code is applicable, please indicate code in brackets.

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

☐ **N/A**

3.0 Product Classification:

☐ Medical Device ☐ Pharmaceutical ☐ Active Pharmaceutical Ingredient ☐ Labware ☐ Botanicals ☐ Food / Spice

☐ Food Packaging ☐ Cosmetics ☐ Animal Food / Pet Treats ☐ Other (define) _____

☐ **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**

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:

STERIS

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Production Signature: _____ **Date:** _____

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