

Sartorius Stedim North America

## Notification letter

### ECN 1917901: Gamma Irradiator Certificate Change

Dear Valued Customer,

## Introduction

As an international leading supplier of process technologies to the biopharmaceutical industry, Sartorius is committed to a continuous improvement of its products and services in order to serve our customers in an optimal way.

This notification letter is intended to inform you about a certificate change of our gamma irradiator.

## Change description

Due to a change of their Operations Data Management System, specifically the Automated-Batch-Approval (ABA) functionality, the Quality Review and Release box found on STERIS Certificate of Processing has been updated. An example of the new certificate is provided in Appendix 1.

Here is an example of Review and Release box:

Previous Review and Release box
<b><u>Signature Manifest</u></b> Reviewed and E-Signed By: <b>Victoria Mullings (QS &amp; RC Technician I)</b> Date/Time E-Signed: 2020-06-10 08:53 AM Document Content Revision: 1
Current Review and Release box
<b>Gamma Process Run Approval authorized by STERIS</b> Procedure 99999, Validation Reference OQ-FRS-100, OQ-FRS-101, OQ-FRS-120

The change isn't affecting the irradiation process, irradiation dose or location of the gamma irradiation. Therefore, this change has no impact on the fit, form or functionality of the product.

## Impacted Products

All New Oxford-manufactured products that are irradiated at the Chester, NY, USA site are impacted by this change. See Appendix 2 for the full list of products.

## Change Implementation

This change is controlled internally and is governed by our change management procedures. The updated approval box on the STERIS Certificate of Processing is effective immediately.

We thank you for your trust and your continuous use of Sartorius Stedim Biotech products.

Sincerely,



Eva Lindskog  
Head of Product Management FMT  
Sartorius Stedim Switzerland AG



Vanessa Nardolillo  
Head of Quality Management & Regulatory Affairs BPS  
Sartorius Stedim FMT SAS

## Appendix 1: Example of certificate

### Previous certificate review box

Processing Run Start Date: 07-Jun-20 04:20 AM	
Processing Run End Date: 07-Jun-20 02:09 PM	
Minimum Specified Dose (kGy): 25.0	Minimum Delivered Dose (kGy): 27.1
Maximum Specified Dose (kGy): 45.0	Maximum Delivered Dose (kGy): 35.3
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.	
<b>Signature Manifest</b> Reviewed and E-Signed By: <b>Victoria Mullings (QS &amp; RC Technician I)</b> Date/Time E-Signed: 2020-06-10 08:53 AM Document Content Revision: 1	
Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.	
<u>Processing Location</u> 23 Elizabeth Drive Chester NY 10918 Phone: 845-469-4087	
Document ID: 24210	
GW1-08-006-15	Last Revised in Rel 2.0.0.0
Rel Date: 11/13/2018	Page 2 of 2

### Current certificate review box

Processing Run Start Date: 01-Sep-20 09:56 PM	
Processing Run End Date: 02-Sep-20 07:45 AM	
Minimum Specified Dose (kGy): 25.0	Minimum Delivered Dose (kGy): 29.3
Maximum Specified Dose (kGy): 45.0	Maximum Delivered Dose (kGy): 37.1
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.	
<b>Gamma Process Run Approval authorized by STERIS</b> Procedure 99999, Validation Reference OQ-FRS-100, OQ-FRS-101, OQ-FRS-120	
Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.	
<u>Processing Location</u> 23 Elizabeth Drive Chester NY 10918 Phone: 845-469-4087	
Document ID: 31123	
GW1-08-006-15	Last Revised in Rel 2.0.0.0
Rel Date: 11/13/2018	Page 1 of 1