

Changenotification_AB@sartorius.comNovember 26th, 2020

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Notification Letter**ECR 20627: Additional sterilization locations for Europe**

Dear Valued Customer,

Introduction

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

This change notification is to inform you about the introduction of alternate sterilization locations for Europe.

Change description

We are pleased to announce that, in line with our strategy of assurance of supply, contingency planning and worldwide capacity of gamma irradiation we are qualifying two new gamma irradiation using Cobalt 60 sub-contracting facilities, Steris, located in Allerhausen & Radeberg (Germany) for the sterilization of products manufactured in our sites of Aubagne (France), Lourdes (France), Gottingen (Germany) and Mohamdia (Tunisia).

Our gamma irradiation sub-contractors for Europe will be:

Status	Name	Location
Current	Ionisos	Sable sur Sarthe (France)
Current	Ionisos	Pouzauges (France)
Current	Steris	Marseille (France)
Current	Steris	Marcoule (France)
New	Steris	Allerhausen (Germany)
New	Steris	Radeberg (Germany)

Steris Allerhausen & Radeberg are ISO 11137-1, ISO13485 certified companies (certificates attached).

The responsibility of providing sterile products continues to reside within Sartorius Stedim Biotech.

We therefore continue to guarantee a 10⁻⁶ Sterility Assurance Level (SAL) established and validated according to the requirements of the ISO 11137-1: Requirements for development, validation and routine control of a sterilization process for medical devices.

To ensure equivalency of the sterilization methodology, the irradiation specifications for minimum and maximum dose remain unchanged.

An executive summary of the validation conducted for the new Steris Allerhausen & Radeberg sites is available and provided with this letter, specifying:

Validation assessment/ summary	Validation of the sterility by Gamma Irradiation at 25-45 kGy of products manufactured by Sartorius Stedim Biotech Aubagne, France, Lourdes, France, Gottingen, Germany and Mohamdia, Tunisia
	Effectiveness of Minimum Dose
	Dose Audits
	Dose Mapping
Certificate of irradiation	Templates

The new sterilization sites are part of the supplier qualification & monitoring program.

Impacted products

Gradually, all products manufactured in our sites of Aubagne, Lourdes (France), Gottingen (Germany) and Mohamdia (Tunisia) can be sterilized at the new location when qualification is completed per product category.

This means that the 2 new irradiation sites can be used for any products with lot numbers starting with:

- From Aubagne, France: Axxxxxxx (A+ 7 numeric digits)
- From Mohamdia, Tunisia: Txxxxxxx (T+ 7 numeric digits)
- From Goettingen, Germany : Gxxxxxxx (G+ 7 numeric digits)
- From Lourdes, France: YYxxx or YYxxx where YY are the last 2 digits of the year + 3 or 4 numeric digits

Change Implementation

With the purpose of fast access to the benefit of this assurance of supply and due to current business capacity in Europe you may start receiving product sterilized by these new sterilization facilities in December 2020. Utilization of these sources will depend on order portfolio, availability of the sterilization facilities and qualification achievement. Service provider identification is mentioned in the Certificate of Irradiation attached to the Certificate of Release provided for each lot.

Should you have any further questions, please do not hesitate to contact your local Application Specialist or Sales Representative.

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

Our FMT gamma irradiation sub-contractors in Europe will be:

Gamma irradiators in Europe	
Steris, Marseille MIN. 712-Arnavaux 13323 Marseille France	Steris, Marcoule Lieu-dit Combe Bertrand, RD 138 30200 Chusclan France
Ionisos Zone Artisanale de l' Aubrée 72300 Sable Sur Sarthe France	Ionisos 31 Rue René Truhaut 85700 Pouzauges France
New: Steris Allershausen GmbH (Synergy Health Allershausen GmbH) Kesselbodenstrasse 7 Allershausen D-85391 Germany	New: Steris Radeberg GmbH (Synergy Health Radeberg GmbH) Juri-Gagarin-Strasse 15 Radeberg D-01454 Germany