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Notification Letter

ECR 21648: Notification on additional sterilization locations for Europe, Sterigenics, Minerbio (Italy)

ECR 21573: Notification on additional sterilization locations for Europe, Steris, Däniken (Switzerland)

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

In order to ensure supply for our customer in a context of a worldwide irradiation capacity restriction, we have developed a contingency program to allow optimum balancing between sites and so maintain delivery lead time. We are pleased to announce that we are qualifying 2 new gamma irradiation facilities using Cobalt 60 sub-contracting, Steris, located in Däniken (Switzerland) and Sterigenics, located in Minerbio (Italy) for the sterilization of products manufactured in our sites of Aubagne (France), Gottingen SSP (Germany) and M'Hamdia (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)
Current	Steris	Allerhausen (Germany)
Current	Steris	Radeberg (Germany)
New	<i>Steris</i>	<i>Däniken (Switzerland)</i>
New	<i>Sterigenics</i>	<i>Minerbio (Italy)</i>

Steris Däniken and Sterigenics Minerbio are ISO 11137-1 and ISO 13485 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) when applicable 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 Däniken and Sterigenics Minerbio sites will be available end of March 2021, providing:

Validation assessment/summary	Validation of the sterility by Gamma Irradiation at 25-45 kGy of products manufactured by Sartorius Stedim Biotech Aubagne (France), Gottingen (Germany) and M'Hamdia (Tunisia)
	Effectiveness of Minimum Dose
	Dose Audits
	Dose Mapping
	Supply Chain Memo (SCM)
Certificate of irradiation	Templates

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

Impacted products

Gradually, all products manufactured in our sites of Aubagne (France), Gottingen SSP (Germany) and M'Hamdia (Tunisia) can be sterilized at these new locations 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 SSP, Germany: Gxxxxxxx (G+ 7 numeric digits) Flexsafe STR® only

The list of our FMT gamma irradiation sub-contractors in Europe is available in Appendix 1.

Change Implementation

This change is controlled internally according to our change management procedures.

Due to the increase in demand and with the purpose of fast access to the benefit of this assurance of supply, this change will be implemented as soon as qualifications are finalized, expected end of March 2021 and the Validation Summary Report will be sent upon request when it is ready.

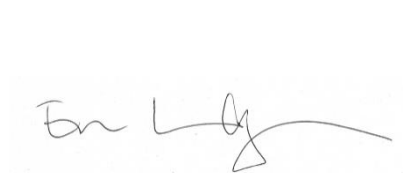
From the end of March 2021, you may start receiving product sterilized by these new sterilization facilities. Utilization of these sources will depend on order portfolio, availability of the sterilization facilities and qualification achievement. Service provider identification is mentioned in the Certificate of Irradiation attached to the Certificate of Release provided for each lot. An example is provided attached to this letter.

Customer specific request for the use of a specific Gamma irradiation provider cannot be considered due to operations and supply chain logistics.

We are looking forward to support you in every way possible. If you have further questions, please do not hesitate to contact your local Application Specialist or Sales representative.

We appreciate 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: 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
Steris Allershausen GmbH (Synergy Health Allershausen GmbH) Kesselbodenstrasse 7 Allershausen D-85391 Germany	Steris Radeberg GmbH (Synergy Health Radeberg GmbH) Juri-Gagarin-Strasse 15 Radeberg D-01454 Germany
New Sterigenics Italy SPA Via Marzabotto 4 Minerbio Bologna 40061 Italy	New Steris Däniken (Synergy Health Däniken AG) Hogenweidstrasse 6 Däniken CH-4658 Switzerland