

Changenotification_AB@sartorius.com

January 27th , 2020

Sartorius Stedim FMT S.A.S.
Zone Industrielle Les Paluds
Avenue de Jouques - CS 91051
13781 Aubagne Cedex, France

t:+33.(0)4.42.84.5600

f:+33.(0)4.42.84.5619

www.sartorius-stedim.com

S.A. au capital de 42 940 121 Euros RCS
de Marseille B 538 760 125
SIRET 538 760 125 00012
TVA FR 39 538 760 125
APE 2222 Z

Sartorius Stedim FMT S.A.S- 13781 Aubagne France

Notification letter

ECR 11124: Design change of the GAMMASART ATD™

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 a design change of the GAMMASART ATD™, following supplier modifications, for the following references:

- Component AC112474 used in bag assemblies
- Stand-alone connectors:
 - AN-CON-101025
 - AN-CON-102025


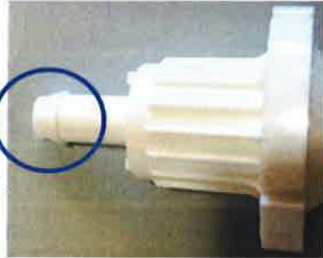
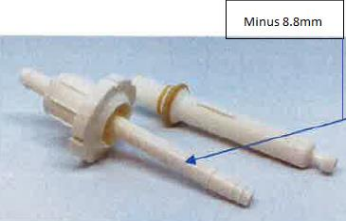


Change description

We have been informed by our supplier about the following design changes on the GAMMASART ATD™:

- Connecting end of the body
- Inner tube
- External shape

For a better traceability regarding compatibility with the connection port versions, the component reference number has also been updated.

SARTORIUS

Description	Before change	After change	Reason
Affected component reference	AN-CON-101025 (only compatible SART System™ port version 1 &2) AN-CON-102025 (only compatible SART System™ port version 1 &2) AC112474 (only compatible with SART System™ port version 1 &2)	AN-CON-121025 (compatible with all SART System™ port versions) AN-CON-122025 (compatible with all SART System™ port versions) 1000070249 (compatible with all SART System™ port versions)	To be compatible with the SART System™ port version 3 and older
Connecting-end of the body from a “Christmas tree” Shape to “Hose barb” shape.			To improve the tightness between the tubing and the connector
The inner tube is made shorter:			To reduce the magnitude of the torque at its basis (where it is welded to the body) when the operator is connecting the tubing inside the working chamber
External shape: - Change of the cover, passing from symmetry 4 to symmetry 2, with shorter splines (a) - Change of the body: 2 additional positioning grooves (b) - Change of the body: reduction from 16 to 8 fins (c)			To allow the GAMMASART ATD™ to be used with the new SART System™ port (fully secured port) while ensuring full compatibility with all previous versions of the SART System™ port.

1000070249:

These design changes have been successfully qualified and validated by Sartorius Stedim to be assembled on our final products. A validation report will be provided upon request.

These changes has no effect on functionality and the quality of the final product.

AN-CON-121025, AN-CON-122025:

As the connection part of the connector will be modified, we advise you to evaluate the impact on your assembly according to your internal procedures for assembly qualification.

Impacted Products

The following products are affected by this change.

For the connector: AC112474

FAT110397	FBT129857	FBT300717	FBT501169	FIS126818	FXB117863
FAT121452	FBT131616	FBT308382	FFB113887	FIS126827	FXB124173
FAT304594	FBT300000	FBT308448	FFB131861	FIS126828	FXB130746
FBT111525	FBT305610	FBT309200	FFB302625	FIS126829	FXB214640
FBT123137	FBT305744	FBT500907	FFB305450	FIS126830	FXB308393
FBT125390	FBT307666	FBT500967	FFB306310	FIS301541	
FBT127792	FBT132458	FBT501016	FFB307162	FMB124329	
FBT129855	FBT307667	FBT501050	FFB308514	FMB124338	
FBT129856	FBT300331	FBT501074	FIS126817	FXB112529	

Stand-alone products:

AN-CON-101025

AN-CON-102025

Change Implementation

1000070249:

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

This change requires the technical drawing (TD) to be revised to reflect the new component in the bill of materials.

This change will be implemented as from June 2021 according to:

- Priority customers which are already owning the SART System™ port version 3.
- Our stock depletion for customers which are still using an old SART System™ port version.

AN-CON-121025, AN-CON-122025:

These products are already available for order and we will also keep the older versions AN-CON-101025 and AN-CON-102025 at your disposal until June 2021 before switching definitively.

We thank you for your trust and your continuous use of Sartorius products and look forward to assisting you in managing this change.

Sincerely,


 Dr Eva Lindskog
 Head of Product Management FMT
 Sartorius Stedim Switzerland AG


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