業務プロセスおよび文書類変更通知 追記

DMS および ERP の SAP への移行

お客様各位:

時下益々ご清祥の段 お慶び申し上げます。また平素より Sartorius Stedim Biotech 製品をご使用いただき感謝申し上げます。8 月 19 日にご通達いたしました「DMS および ERP の SAP への移行」の進捗を以下にまとめました。ご照査の上、ご査収ください。

変更内容

1. 使用期限算出方法の統一

この変更は製品の使用期限の変更ではありません。

オーバーニュおよびモハメディア工場の SAP®統合により使用期限のシステム内算出方法が以下の様に統合されます。この算出はシステム内で自動的に行われます。

使用期限＝SAP 内への Lot 番号登録日＋製品使用期限

2. バッチ番号付番方法

新しいバッチ番号の付番方法は最終組み立てを実施した工場により異なります。

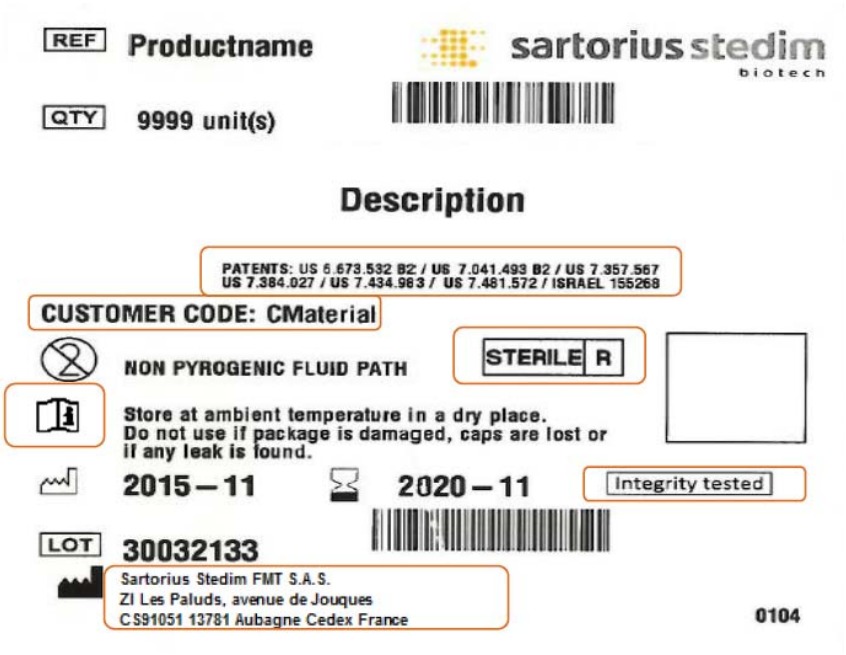
1) フランス オーバーニュ工場の場合　Axxxxxxx（A＋7 つの数字）
2) チュニジア モハメディア工場の場合　Txxxxxxx（T＋7 つの数字）
   注:最終出荷につきましてはオーバーニュ工場のままです
3) プエルトリコ ヤウコ工場の場合　1601P001
   16:製造年
   01:製造月
   P:工場（P＝プエルトリコ）
   001:製造順番号

また、プロトタイプ製品につきましては以下の付番方法になります。

4) フランス オーバーニュ工場の場合　PRAxxxxx（PRA＋5 つの数字）
5) チュニジア モハメディア工場の場合　PRTxxxxx（PRT＋5 つの数字）

3. 最終製品ラベルの統一

標準製品の製品ラベルは以下の様に統一されます。



赤字で囲まれた部分は製品により表示されない場合や表記が変更になる場合があります。
ラベル上の情報内容につきましては製品群により異なります。


の横の表記は製造工場により異なります。

フランス オーバーニュ工場の場合
Sartorius Stedim FMT S.A.S.
ZI Les Paluds, avenue de Jouques
CS91051 13781 Aubagne Cedex France

プエルトリコ ヤウコ工場の場合
Sartorius Stedim Filters Inc, 00698
Yauco, Puerto Rico-0006

カスタマイズ品については製品群やお客様のご要望により上記のラベル表記とは異なる場合があります。

4. Certificate Of Release（COR）フォーマットの統一

Certificate Of Release は製品群ごとに統一されたフォーマットに変更されます。

製品群の名称がこの位置に
記載されます。
記載方法：GAMxxx
（x は製品名）

この部分に製造工場の
住所等が記載されます。


CERTIFICATE OF RELEASE

Product Description:

Specifications:

フランス オーバーニュ工場の場合
Sartorius Stedim FMT S.A.S. / ZI Les Paluds, avenue de Jouques
CS91051 / 13781 Aubagne Cedex France
Phone : + 33.4.42.84.6.00 – fax: + 33.4.42.84.56.19

プエルトリコ ヤウコ工場の場合
P.O. Box 6 Yauco, Puerto Rico 00698-0006 / Road 128 Int. 368 Km. 12.9 Lot 6,
Bo Susua Baja, Susua Industrial Park, Yauco, Puerto Rico
Phone : + 1.787.856.5020 – fax: +1.631.253.5124

以下の製品群の新しい Certificate Of Release サンプルを添付いたします

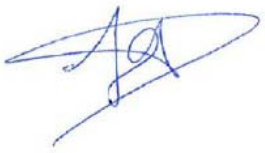
- －Flexboy®
- －Flexel® / Flexel® 2D
- －Flexsafe®
- －Cultibag STR 50 – 200L
- －Cltibag STR 500 – 1000L
- －Flexsafe® STR 50 – 200L
- －Flexsafe® STR 500 – 2000L
- －Components

変更時期

SAP の稼動開始日は、当初の予定通り 2016 年 11 月 1 日となります。Certificate Of Release フォーマット変更の実施は 11 月 1 日以降順次開始されます。

今後とも弊社製品をどうぞよろしくお願いいたします。

以上



Isabelle Quintard
Senior Manager,
Continuous Quality Improvement
Sartorius Stedim FMT SAS

Anne-Laure Moreau
Change Notification Manager
Sartorius Stedim Biotech

Flexboy®

sartorius stedim biotec

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

==========

Specifications:

STATEMENTS

Biological Reactivity Tests in vitro and in vivo:	SARTORIUS STEDIM Biotech bags have passed USP <87> and USP <88> testing and are classifiec USP Class VI.
Physicochemical Test:	SARTORIUS STEDIM Biotech bags have passed current USP <661> tests for plastic Containers. EVAM®, the contact layer of the S71 film passes current EP 3.1.7 (Polyethylene Vinyl-Acetate) and complies with FDA 21CFR177.1350.
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev 3 and the European Pharmacopoeia (EP) 5.2.8

MONITORING

Endotoxins:	Representative Finished Product has been sampled and tested according to current USP <85> Bacterial Endotoxins test by LAL and EP 2.6.14 method D. Passes the acoeptance criteria of < 0.125 EU/mL.
Particulates:	Representative Finished Product has been sampled and tested according to current USP <788> and EP 2.9.19. Passes the Large Volume Injectables limits.
Bioburden:	Representative Finished Product has been sampled and tested according to ISO 11737 method by filtration. Passes the acoeptance limits determined by validation.
Sterility:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING

Visual Inspection:	100% of these bags are inspected and pass the SARTORIUS STEDIM Biotech specifications.
Leak test:	100% of these bags are leak tested.
Product Conformity:	Technical drawing compliance and Batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation Certificate from the approved sub-contractor is enclosed.

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We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations.

Ref.: GAMFLEXBO

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

Zone Industrielle Les Paluds
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Fax +33.4.42.84.56.19
www.sartorius-stedim.com

Flexel®

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

==========

Specifications:

STATEMENTS

Biological Reactivity Tests in vitro and in vivo:	SARTORIUS STEDIM Biotech Flexel bags have passed USP <87> and USP <88> testing and are classified USP Class VI.
Physicochemical Test:	SARTORIUS STEDIM Biotech Flexel bags have passed current USP <661> tests for plastic Containers. PE, the contact layer of the S40 film passes current EP 3.1.5 (Polyethylene with additives) and complies with U.S. FDA 21CFR177.1520(c)3.2a.
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev 3 and the European Pharmacopoeia (EP) 5.2.8.

MONITORING

Endotoxins:	Representative Finished Product has been sampled and tested according to current USP <85> Bacterial Endotoxins test by LAL and EP 2.6.14 method D. Passes the acceptance criteria of < 0.125 EU/mL.
Particulates:	Representative Finished Product has been sampled and tested according to current USP <788> and EP 2.9.19. Passes the Large Volume Injectables limits.
Bioburden:	Representative Finished Product has been sampled and tested according to ISO 11737 method by filtration. Passes the acceptance limits determined by validation.
Sterility:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING

Visual Inspection:	100% of these bags are inspected and pass the SARTORIUS STEDIM Biotech specifications.
Product Conformity:	Technical drawing compliance and Batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation Certificate from the approved sub-contractor is enclosed.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations.

Ref.: GAMFLEXEL

Note: Comment

09.09.9999

Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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sartorius stedim biotech

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

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Specifications:

STATEMENTS

Biological Reactivity Tests in vitro and in vivo:	SARTORIUS STEDIM Biotech Flexel bags have passed USP <87> and USP <88> testing and are classified USP Class VI.
Physicochemical Test:	SARTORIUS STEDIM Biotech Flexel bags have passed current USP <661> tests for plastic Containers. PE, the contact layer of the S40 film passes current EP 3.1.5 (Polyethylene with additives) and complies with FDA 21CFR177.1520(c)3.2a.
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev 3 and the European Pharmacopoeia (EP) 5.2.8.

MONITORING

Endotoxins:	Representative Finished Product has been sampled and tested according to current USP <85> Bacterial Endotoxins test by LAL and EP 2.6.14 method D. Passes the acceptance criteria of < 0.125 EU/mL.
Particulates:	Representative Finished Product has been sampled and tested according to current USP <788> and EP 2.9.19. Passes the Large Volume Injectables limits.
Bioburden:	Representative Finished Product has been sampled and tested according to ISO 11737 method by filtration. Passes the acceptance limits determined by validation.
Sterility:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING

Visual Inspection:	100% of these bags are inspected and pass the SARTORIUS STEDIM Biotech specifications.
Leak test:	100% of these bags are leak tested
Product Conformity:	Technical drawing compliance and Batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation Certificate from the approved sub-contractor is enclosed.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations.

Ref.: GAFLEXE2D

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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Flexsafe®

sartorius stedim biotech

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

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Specifications:

STATEMENTS

Biological Reactivity in vitro and in vivo tests:	SARTORIUS STEDIM Biotech Flexsafe® bags have passed USP <87> and USP <88> testing and are classified USP Class VI.
Physicochemical properties:	SARTORIUS STEDIM Biotech Flexsafe® bags have passed USP <661> tests for plastic Containers. The contact layer of the S80 film have passed EP 3.1.5 (Polyethylene with additives) and complies with U.S. FDA 21CFR177.1520.(c).
TSE-BSE:	Conform to the European Guidance EMA/410/01 rev 3 and the European Pharmacopoeia (EP) 5.2.8.
Cell Growth:	SARTORIUS STEDIM Biotech Flexsafe® bags have passed the SSB cell growth standardized assay.

MONITORING

Endotoxins:	Representative product has been tested according to USP <85> Bacterial Endotoxins Test by LAL and EP 2.6.14 method D. Passes the acceptance criteria of <0.125 EU/mL.
Particulates:	Representative product has been tested according to USP <788> and EP 2.9.19. Passes the Large Volume Injectables limits.
Bioburden:	Representative product has been tested according to ISO 11737 method by filtration. Passes the acceptance limits determined by validation.
Sterility:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING

Visual Inspection:	100% of these bags are inspected and pass the SARTORIUS STEDIM Biotech specifications.
Leak Test:	100% of these bags are leak tested.
Product Conformity:	Technical drawing compliance and Batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation Certificate from the approved sub-contractor is enclosed.

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We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations.

Ref.: FSAFE2DP1

Note: Comment

09.09.9999

Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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www.sartorius-stedim.com

Cultibag STR 50L to 200L

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

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Specifications:

STATEMENTS

Biological Reactivity in vitro and in vivo tests:	All fluid contact materials of construction used for Cultibag Bioreactor meet the requirements of the USP Biological Reactivity tests USP <87> and USP <88> and are classified USP Class VI.
Physicochemical Test:	The CultiBag STR contact layer of the film passes the EP 3.1.5 (Polyethylene with additives) and complies with U.S. FDA 21CFR177.1520.(c) 3.2a.
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev. 3 and the European Pharmacopoeia (EP) 5.2.8.

MONITORING

Production Conditions:	All products have been manufactured under controlled conditions in an ISO 7 cleanroom environment.
Bioburden:	Representative Product has been tested according to ISO11737 method by filtration. Passes the acceptance limits determined by validation.
Sterility:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level(SAL).

BATCH TESTING

Visual Inspection:	Each bag is individually inspected during production and passes SARTORIUS STEDIM specification.
Product Conformity:	Technical drawing compliance and batch record review.
Gamma Irradiation:	25kGy minimum. The Gamma irradiation Certificate from the approval Sub-contractor is enclosed, except filter lines that are autoclaved, delivered separately.
DO and pH sensors:	All single-use sensors installed on the product have been pre-calibrated with calibration parameters mentioned on the label on the bag.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations. Ref.: GAMSTRBB

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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Cultibag STR 500L to 1000L

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

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Specifications:

STATEMENTS

Biological Reactivity in vitro and in vivo tests:	All fluid contact materials of construction used for Cultibag Bioreactor meet the requirements of the USP Biological Reactivity tests USP <87> and USP <88> and are classified USP Class VI.
Physicochemical Test:	The CultiBag STR contact layer of the film passes the EP 3.1.5 (Polyethylene with additives) and complies with U.S. FDA 21CFR177.1520.(c)3.2a.
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev. 3 and the European Pharmacopoeia (EP) 5.2.8.

MONITORING

Production Conditions:	All products have been manufactured under controlled conditions in an ISO 7 cleanroom environment.

BATCH TESTING

Visual Inspection:	Each bag is individually inspected during production and passes SARTORIUS STEDIM specification.
Product Conformity:	Technical drawing compliance and batch record review.
Gamma Irradiation:	25kGy minimum. The Gamma irradiation Certificate from the approval Sub-contractor is enclosed, except filter lines that are autoclaved, delivered separately.
DO and pH sensors:	All single-use sensors installed on the product have been pre-calibrated with calibration parameters mentioned on the label on the bag.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations. Ref.: GAMSTRSBB

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

==========

Specifications:

STATEMENTS

Biological Reactivity in vitro and in vivo tests:	All fluid contact materials of construction used for Flexsafe® Bioreactor meet the requirements of the USP Biological Reactivity tests USP <87> and USP <88> and are classified USP Class VI.
Physicochemical Test:	PE contact layer of film for Flexsafe® Bioreactor bags passed USP <661> tests for plastic Containers, EP 3.1.5 and complies with U.S. FDA 21CFR177.1520(c).
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev. 3 and the European Pharmacopoeia (EP) 5.2.8.
Cell Growth:	SARTORIUS STEDIM Biotech Flexsafe® bags have passed the SSB cell growth standardized assay during film qualification.

MONITORING

Production Conditions:	All products have been manufactured under controlled conditions in an ISO 7 cleanroom environment.
Bioburden:	Representative Product has been tested according to ISO 11737 method by filtration. Passes the limits determined by validation.
Sterility Assurance:	According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility acceptanc Assurance Level(SAL).

BATCH TESTING

Visual Inspection:	Each bag is individually inspected during production and passes SARTORIUS STEDIM specification.
Product Conformity:	Technical drawing compliance and batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation certificate from the approval Sub-contractor is enclosed except filter lines that are autoclaved, delivered separately.
DO and pH sensors:	All single-use sensors installed on the product have been pre-calibrated with calibration parameters mentioned on the label on the bag.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations. Ref.: GSTRSAFBB

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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www.sartorius-stedim.com

sartorius stedim biotech

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

==========

Specifications:

STATEMENTS

Biological Reactivity in vitro and in vivo tests:	All fluid contact materials of construction used for Flexsafe® Bioreactor meet the requirements of the USP Biological Reactivity tests USP <87> and USP <88> classified USP Class VI.
Physicochemical Test:	PE contact layer of film for Flexsafe® Bioreactor bags passed USP <661> tests for plastic Containers, EP 3.1.5 and complies with U.S. FDA 21CFR177.1520(c).
TSE-BSE status:	Conform to the European Guidance EMA /410/01 rev. 3 and the European Pharmacopoeia (EP) 5.2.8.
Cell Growth:	SARTORIUS STEDIM Biotech Flexsafe® bags have passed the SSB cell growth standardized assay during film qualification.

MONITORING

Production conditions:	All products have been manufactured under controlled conditions in an ISO 7 cleanroom environment.

BATCH TESTING

Visual Inspection:	Each bag is individually inspected during production and passes SARTORIUS STEDIM specification.
Product conformity:	Technical drawing compliance and batch record review.
Gamma Irradiation:	25 kGy minimum. The Gamma Irradiation Certificate from the approval Sub-contractor is enclosed, except filter lines that are autoclaved, delivered separately.
DO and pH sensors:	All single-use sensors installed on the product have been pre-calibrated with calibration parameters mentioned on the label on the bag.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations. Ref: IRSTRSAFE

Note: Comment

09.09.9999
Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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Fax +33.4.42.84.56.19
www.sartorius-stedim.com

Components

sartorius stedim biotech

CERTIFICATE OF RELEASE

Product Description:

Product description:	DESCRIPTION		
Reference:	REFERENCE		
Batch number:	XXXXXXXX	Quantity:	99999
Expiry date:	YYYY - MM	Revision level:	NN
Customer part number:	CUSTOMER PART NUMBER		
Irradiation batch (cert. enclosed):	IRRADIATION BATCH NUMBER		

==========

Specifications:

STATEMENTS

TSE-BSE status: Conform to the European Guidance EMA /410/01 rev 3 and the European Pharmacopoeia (EP) 5.2.8.

MONITORING

Sterility: According to ISO 11137: Sterilization of health care products - Radiation with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING

Product Conformity: Technical drawing compliance and Batch record review.

Gamma Irradiation: 25 kGy minimum. The Gamma Irradiation Certificate from the approved sub-contractor is enclosed.

==========

We certify that this batch has been manufactured in compliance with our internal procedures and that all the test results conform to our specifications. This batch has been manufactured following applicable cGMP regulations. Ref.: GAMCOMP

Note: Comment

09.09.9999

Date of Release

Quality Specialist
QUALITY DEPARTMENT

ISO 9001 certified
ISO 13485 certified
FDA registered

Manufactured by
Sartorius Stedim FMT S.A.S.

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