

changenotification\_ab@sartorius.com

2021-03-18

Sartorius Stedim Lab Ltd  
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[www.sartorius.com](http://www.sartorius.com)

Sartorius Stedim Lab Ltd, Stonehouse GL10 3UT, UK

Registered in England & Wales  
with  
company number 02732279

VAT number GB613854539

## Notification Letter

**ECR 021739****Additional sterilisation location for UK**

Dear Valued Customer,

As an international leading supplier of process technologies to the bio-pharmaceutical industry, Sartorius Stedim Lab Ltd 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 an additional sterilisation facility within the United Kingdom.

### 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 an additional gamma irradiation facility using Cobalt 60, sub-contracting to Synergy Health Sterilisation Ltd, (part of the Steris group), located in Bradford United Kingdom for the sterilisation of products manufactured within our site in Stonehouse United Kingdom

Current Sterilisation site	New Sterilisation site
BGS Beta-Gamma-Service GmbH & Co.  John-Deere-Straße 3, 76646 Bruchsal, Germany	Synergy Health Sterilisation UK Limited, a STERIS Company Roydsdale Way Euroway Trading Estate Bradford, West Yorkshire, United Kingdom

Steris Bradford is an ISO 11137-1 and ISO13485 certified company (certificates attached in Appendix 02).

ECR 21739

The responsibility of providing irradiated/sterile products continues to reside within Sartorius Stedim Lab Ltd.

We therefore continue to guarantee equivalency for Sterility Assurance Levels (SAL) previously established and validated according to the requirements of the ISO 11137-1: Including requirements for development, validation and routine control of a sterilisation process for our irradiated devices.

The Validation Summary Report will be available in March 2021 upon customer request.

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

Equivalency comparison table for Biosart 100 Family of Products		
Equivalency Parameter	BGS	Steris
Required Dose kGy	Min 25.0kGy Max 50kGy	Min 25.0kGy Max 50kGy
Dimension of Shipper (avg)	L: 660 W:380 H:735	L: 660 W:380 H:730
Dimensions of product on pallet (mm)	L:1040 W:760 H:1620	L:1040 W:760 H:1620
Weight Range Pallet + Product	154 Kg	123.1 – 137.2 Kg
Density Range	0.117 g/cm <sup>3</sup>	0.09 – 0.10 g/cm <sup>3</sup>

Equivalency comparison table for Microsart @ Filter 100 Family of Products		
Equivalency Parameter	BGS	Steris
Required Dose kGy	Min 15.0kGy Max 30kGy	Min 15.0kGy Max 30kGy
Dimension of Shipper (avg)	L: 630 W:570 H:370	L: 650 W:570 H:370
Dimensions of product on pallet (mm)	L:1140 W:740 H:1780	L:1145 W:740 H:1830
Weight Range Pallet + Product	122 Kg	124.4 Kg
Density Range	0.074 g/cm <sup>3</sup>	0.07 g/cm <sup>3</sup>

Equivalency comparison table for Microsart @ Filter 250 Family of Products		
Equivalency Parameter	BGS	Steris
Required Dose kGy	Min 15.0kGy Max 30kGy	Min 15.0kGy Max 30kGy
Dimension of Shipper (avg)	L: 630 W:570 H:370	L: 650 W:570 H:370
Dimensions of product on pallet (mm)	L:1140 W:740 H:1780	L:1145 W:740 H:1830
Weight Range Pallet + Product	122 Kg	128.8 Kg
Density Range	0.074 g/cm <sup>3</sup>	0.07 g/cm <sup>3</sup>

The new sterilisation site is part of the Sartorius supplier qualification & monitoring program.

### Impacted products

Gradually, all products manufactured at our site Stonehouse United Kingdom can be irradiated/sterilised at the new location when qualification is completed per product category.

This means that the new irradiation site can be used for any products with lot numbers ending with a 7 which is the site identifier for SSL Stonehouse UK.

For Stonehouse: 9 numerical digits (YYWWNNNN7, YY=Year, WW=Week, NNNN=Running Number, 7=Location code for Stonehouse) an example lot number being: - 211200187.

Please find below the list of impacted products (Appendix 01).

### Change Implementation

With the purpose of fast access to the benefit of this assurance of supply and due to current business capacity in Europe and UK you may start receiving product sterilised by this new sterilisation facility in **April 2021**. Utilisation of these sources will depend on order portfolio, availability of the sterilisation 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,



i.V. Fiona Coats  
Head of Marketing LPS  
Sartorius Stedim Biotech



i.V. Susanne Gerighausen  
Head of Quality Assurance &  
Control LPS  
Sartorius Lab Instruments  
GmbH & Co.KG

## Appendix 01

Material	Material Description
16401-47-06--ACK	BS 100 Monitor,CN white-black,0.45Åµ,48P
16401-47-06--G4K	Biosart 100 Monitor, white, 0.45µm, 16x3
16401-47-06----K	BS 100 Monitor, CN white-black, 0.45 Åµm
16401-47-06-V--K	BS 100 Monitor, CN white-black, 0.45 Åµm
16401-47-07--ACK	BS 100 Monitor, CN white-black, 0.2 Åµm
16401-47-07----K	BS 100 Monitor, CN white-black, 0.2 Åµm
16401-47-H6----K	BIOSART 100 0.45Åµ WHITE/BLACK GRID 48PK
16401-47-H6-V--K	BS 100 Monitor, CN white-black, 0.45 Åµm
16402-47-06--ACK	BS 100 Monitor, CN green-d.gr., 0.45 Åµm
16402-47-06----K	BS 100 Monitor, CN green-d.gr., 0.45 Åµm
16403-47-04----K	BS 100 Monitor, CN gray-white, 0.8 Åµm
16403-47-04-V--K	BS 100 Monitor, CN gray-white, 0.8Åµ 48p
16403-47-06--ACK	BS 100 Monitor, CN gray-white, 0.45 Åµm
16403-47-06----K	BS 100 Monitor, CN gray-white, 0.45 Åµm
16403-47-06-V--K	BS 100 Monitor, CN gray-white, 0.45 Åµm
16404-47-06--G4K	BS 100 Monitor, RC white, 0.45 µm, 16x3
16404-47-06----K	BS 100 Monitor, RC white, 0.45 Åµm, 50pk
16D00--10-H6--BL	MS @filter 100ml, CN, 0,45 µm, HF, white
16D01--10-06--BL	MS ADDfilter100,CN white-black,0.45µm
16D01--10-06--TG	MS ADDfilter 100,CN,white/black,0.45 µm
16D01--10-07-ACG	ADDfilter 100,CN, white-black, 0.2µm, si
16D01--10-07--BL	MS ADDfilter 100,CN white-black,0.2µM
16D01--10-07--TG	MS ADDfilter 100, CN white-black, 0.2 Åµm
16D01--10-H6-ACG	ADDfilter 100,CN, white-black,0.45µm HF
16D01--10-H6--BJ	ADDfilter100,CN,white-black,0.45µm HF,XL
16D01--10-H6--BL	MS ADDfilter100,CN white-black,0.45µM HF
16D01--10-H6--TG	MS ADDfilter 100,CN white-black, 0.45 µm
16D01--25-06--BK	MS ADDfilter250,CN white-black,0.45µm
16D01--25-07-ACF	ADDfilter 250,CN, white-black,0.2µm , si
16D01--25-07--BK	MS ADDfilter 250,CN white-black,0.2µm
16D01--25-07--TF	MS ADDfilter 250, CN white-black, 0.2 Åµm
16D01--25-H6-ACF	ADDfilter 250,CN, white-black,0.45µm HF,
16D01--25-H6--BK	MS ADDfilter250,CN white-black,0.45µm HF
16D01--25-H6--BS	ADDfilter 250,CN white/black,0.45µmHF,XL
16D01--25-H6--TF	MS ADDfilter 250, CN white-black, 0.45Åµ

16D02--10-06--BL	MS ADDfilter100,CN green-darkgreen,0.45μ
16D02--10-06--TG	MS ADDfilter 100, CN green-green, 0.45Åμ
16D02--25-06--BK	MS ADDfilter250,CN green-darkgreen,0.45μ
16D02--25-06--TF	MS ADDfilter 250, CN green-green, 0.45Åμ
16D03--10-H6-ACG	ADDfilter 100,CN, black-white,0.45μm HF
16D03--10-H6--BL	MS ADDfilter100,CN black-white,0.45μM HF
16D03--10-H6--TG	MS ADDfilter 100, CN grey-white, 0.45Åμm
16D03--25-05--BK	MS ADDfilter 250,CN grey-white,0.65μM
16D03--25-05--TF	MS ADDfilter 250, CN grey-white, 0.65Åμm
16D03--25-H6-ACF	ADDfilter 250,CN, black-white,0.45μm HF,
16D03--25-H6--BK	MS ADDfilter 250,CN grey-white,0.45μM HF
16D03--25-H6--BS	ADDfilter 250,CN grey-white,0.45μm HF, X
16D03--25-H6--TF	MS ADDfilter 250, CN grey-white, 0.45Åμm
16D04--10-06-ACG	MS ADDfilter 100, PVDF white/plain, sing
16D04--10-06--BL	MS ADDfilter100, PVDF, 0.45μm
16D04--10-06--TG	MS ADDfilter100, PVDF, 0.45μm, Tray
16D05--10-06--BL	MS ADDfilter 100,RC white plain,0.45μM
16D05--10-06--TG	MS ADDfilter 100, RC white plain,0.45 Åμ
16D06--10-06--BL	Microsart @filter 100, 0.4μm PC, 60 pack
16D06--10-06M-BL	Microsart @filter 100, 0.4μm PC, 60 pack
16D06--25-07--BK	Microsart ADDfilter 250,PC,0.2μm,bag

## Appendix 02

**bsi.**

  
By Royal Charter

## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

STERIS Applied Sterilization  
Technologies  
5960 Heisley Road  
Mentor  
Ohio  
44060  
USA

Holds Certificate Number: **MD 741352**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The provision of contract gamma, electron beam and X-ray irradiation sterilization services fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.  
The provision of a contract ethylene oxide sterilization service fulfilling applicable quality management system requirements within EN ISO 11135:2014.  
The provision of contract vapourised hydrogen peroxide sterilization services.  
The provision of distribution services for the purpose of medical device storage.  
The provision of laboratory testing services.  
The provision of cross-linking modification of polymers and experimental irradiation processes.  
The provision of irradiation for testing gamma to customer requirements.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-12-21  
Latest Revision Date: 2020-12-21

Effective Date: 2020-12-21  
Expiry Date: 2021-07-17

Page: 1 of 7

 

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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory).

Information and Contact:  
BSI Group The Netherlands B.V., John H. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3466 780  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

STERIS Applied Sterilization  
Technologies  
5960 Heisley Road  
Mentor  
Ohio  
44060  
USA

Holds Certificate Number:

**MD 77332**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The provision of contract gamma, electron beam and X-ray irradiation processing services in accordance with EN ISO 11137-1:2015.  
The provision of contract ethylene oxide processing services in accordance with EN ISO 11135:2014.  
The provision of contract vaporised hydrogen peroxide sterilization services.  
The provision of distribution services for the purpose of medical device storage.  
The provision of laboratory testing services.  
The provision of cross-linking modification of polymers and experimental irradiation processes.  
The provision of irradiation for testing gamma to customer requirements.

*Gary E Slack*

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-08-13

Latest Revision Date: 2020-12-07

Effective Date: 2018-07-18

Expiry Date: 2021-07-17

Page: 1 of 7



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: +44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

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<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 10-Feb-2021

UK32S12531441-1-1

This is to certify that Bradford Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 Quality System - Medical Devices

Sartorius Stedim Lab Ltd  
Sperry Way  
Stonehouse Park  
Stonehouse  
Gloucestershire GL10 3UT  
UNITED KINGDOM

### Order Information

Account Number:	100459
Synergy Health Sales Part Reference:	1134037
Customer Reference Number:	4560812947
Product Description:	BIOSART 100 MONITOR
Quantity Received:	3
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	50.0
Customer Unit Lot/Batch Number:	H/DENS VALIDATION 16403-47-04—K BATCH 210200827 , 16401-47-06—K BATCH 210200897 WED 27 JAN 21
Other Process Details:	16403-47-04—K Batch 210200827 X1 Pits 16403-47-06—K Batch 210200897 X2 Pits
	Released against validation PQ 1.0542
	Actual minimum dose 26.8kGy
	Actual maximum dose 36.7kGy

### Irradiation Data

Date and Time of Irradiation:	29-JAN-2021 14:22
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Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069

Page 1 of 1

ECR 21739



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<http://www.steris-ast.com>

## Certificate of Irradiation

Date Issued: 22-Feb-2021

UK32S12535387-1-1

This is to certify that Bradford Synergy Health PLC, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products  
EN ISO 13485 Quality System - Medical Devices

Sartorius Stedim Lab Ltd  
Sperry Way  
Stonehouse Park  
Stonehouse  
Gloucestershire GL10 3UT  
UNITED KINGDOM

### Order Information

Account Number:	100459
Synergy Health Sales Part Reference:	1134102
Customer Reference Number:	4560816936
Product Description:	MICROSART FILTER BAG (-BL & -BK)
Quantity Received:	3
Customer Minimum Specification kGy:	15.0
Customer Maximum Specification kGy:	30.0
Customer Unit Lot/Batch Number:	VALIDATION 16D01-25-H6-BK 210200777, 16D03-25-H6-BK 210300417, MON 08 FEB 2021
Other Process Details:	Released against validation PQ 1.0546
	Actual minimum dose 17.2kGy
	Actual maximum dose 23.0kGy

### Irradiation Data

Date and Time of Irradiation:	10-FEB-2021 03:37
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Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

Processing Site: Roysdale Way, Euroway Trading Estate, Bradford, BD4 6SE Phone No: +44 (0) 1274 686011

Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069

Page 1 of 1

ECR 21739