



Change Control Notification - Update

Marlborough MA, USA, 15 May 2020

TW392538-W

Regarding: Branding update to Labels and Certificates of Quality

Dear Customer,

As part of our change control program, we hereby notify you of changes to labels and the Certificates of Quality for standard and custom single-use assemblies manufactured at the Westborough, MA site.

Affected products

The products involved include all standard and custom, single-use products for:

- WAVE Bioreactor™ Cellbags™, M*bags and irradiated accessories
- ÄKTA™ready and ÄKTA™ readyflux flow kits
- ReadyCircuit™ assemblies, including bags, tube sets and filter assemblies
- ReadyToProcess™ Hollow Fiber cartridges and accessories
- Xuri™ cellbags™
- Hollow Fiber Filters

Change description

Labels and Certificates of Quality will be updated with the Cytiva name including logo. Examples of updated certificates and labels are included with this notification.

Reason for the change

Following the Danaher Corporation's purchase of the GE Healthcare Life Sciences Biopharma business units consisting of BioProcess, Cell & Gene Therapy and Genomics & Cellular Research, our company name is now changed to Cytiva. For more information please see change control notification "GE Healthcare Life Sciences (Biopharma business) is now Cytiva" dated 1 April 2020.



Impact of change

Labels and certificates will be updated with the Cytiva name including logo. Please note that finished products in our warehouses are rotated on a regular basis using first expired, first out inventory management and will not be re-labeled. During the transition phase, documents for products or services will be changed gradually in the coming year.

Mixed branding on products (shipments with differently branded products within the same shipment and/or a product carrying both brands) will occur during the transition phase. For products with a longer shelf life (>2 years) the transition phase can last for multiple years.

Please prepare to receive certain goods with brand name for both Cytiva and GE Healthcare Life Sciences for a period of time. Please ensure that your warehouse and Quality Control release personnel are informed and take necessary actions.

Implementation of change

The new labels and certificates will be implemented on 15 June 2020 to coincide with the Dose Range change control notification (200403MXWM-1) which was sent out to affected customers on 03 April 2020.

More Information

For updated information related to our transition into Cytiva, such as answers to frequently asked questions, legal entity updates and other relevant information, please visit www.cytiva.com/4customers.

Attachment

- See attachments 1-6 for label and Certificate of Quality examples for each product line.

While your organization is assessing the potential impact of these changes, please do not hesitate to contact your regional sales office or us at RegulatorySupport@cytiva.com.

Yours sincerely,


A handwritten signature in cursive script that reads "Sarah Cote".

Sarah Cote
Regulatory Support Manager
Cytiva (formerly GE Healthcare Life Sciences)



ATTACHMENT 1: ÄKTA™ Label and Certificate of Quality example:

Old Label

GE Healthcare 

29-1873-81  Flow Kit RM

Serial No. 70020303084 ÄKTAreadyflux

Expire Date: 20211011

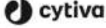
Lot No. 17104949

MADE IN USA

Global Life Sciences Solutions USA LLC
14 Walkup Drive
Westborough, MA 01581
Product Certification can be found at:
www.gelifesciences.com/certificates

291873817002030308420211011

New Label

 **ÄKTA™ readyflux™**

Flow Kit RM

Code no. 29-1873-81

Lot No: 17104949

Serial No: 30000060

Expires: 20211113

Notes:

30000060

Product Certification can be found at:
cytiva.com/certificates

Global Life Sciences Solutions USA LLC
14 Walkup Drive
Westborough, MA 01581 USA
Country of Origin: USA
cytiva.com

New Certificate of Quality

Certificate of Quality

Product: ÄKTA™ readyflux Flow Kit ReadyMate™ Enabled

Lot Number: _____ Product Code Number: _____

Date of Manufacture: _____ Product Description: _____

Expiration Date: _____

Product Release Criteria

We hereby certify that the defined product has been manufactured to meet its specifications and have been verified to meet predetermined Critical to Quality attributes and the flow kit has been formally released for delivery.

Test/Characteristic	Specification	Frequency
INTEGRITY TEST		
Air Leakage (high pressure sections)	$\Delta p < 0.1$ bar/min @ 4.0 bar (3 min)	100%
Air Leakage (low pressure sections)	$\Delta p < 0.1$ bar/min @ 0.5 bar (3 min)	100%
MICROBIOLOGICAL CONTROL		
Gamma Sterilization	27.5 – 40 kGy	Dosimetric Release

Regulatory Conformance


Bio-safety
All polymeric materials in contact with process fluid are animal origin free or in compliance with EMA/410/01 Rev. 3.
All polymeric materials in contact with process fluid meet:

- USP <88> Biological reactivity tests, In Vivo, Class VI

Country of Origin: USA

This product is manufactured in compliance with our ISO 9001 certified quality management system.

Issued by Cytiva Westborough Quality Assurance
This document has been electronically produced and is valid without a signature.
ÄKTA and ReadyMate are the trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.
Cytiva and the Droo logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate.



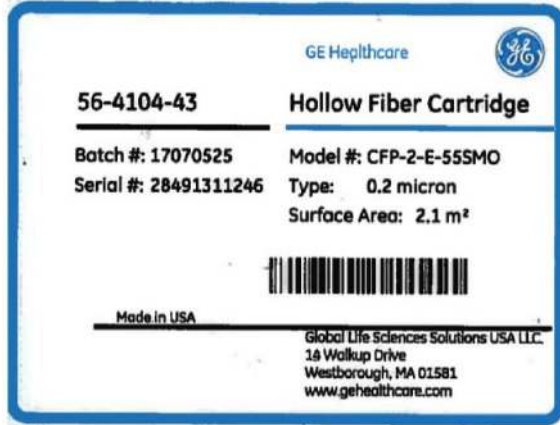
Global Life Sciences Solutions USA LLC
14 Walkup Drive
Westborough, MA 01581 USA

cytiva.com 29254153 Rev AD

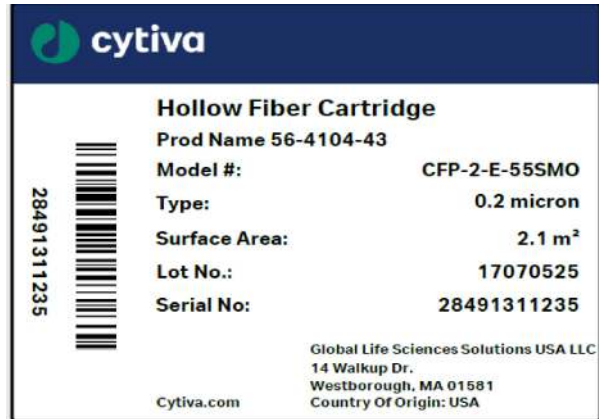


ATTACHMENT 2: Hollow Fiber Filter Label and Certificate of Quality example:

Old Label



New Label

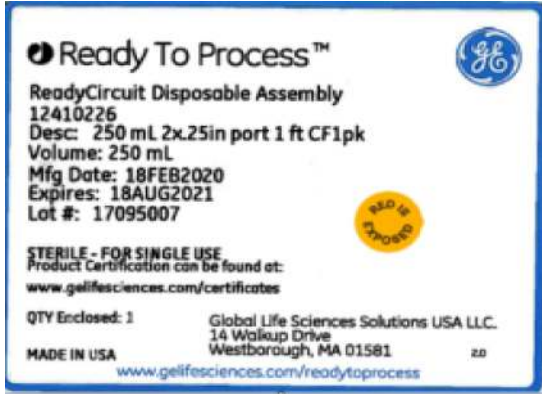


New Certificate of Quality

Certificate of Quality		
Product: Hollow Fiber Cartridge	Product Code Number:	
Batch Number:	Product Catalog Number:	
Date of Manufacture:		
Product Release Criteria		
The membrane and product above have met the following specifications established by Cytiva.		
Test/Characteristic	Specification	Test Frequency
HYDRAULIC TEST Clean Water Permeability @ 25°C	≥400 gfd/psig ≥9980 LMH/barg	Batch Sample
INTEGRITY TEST Device	Pass	Each Unit
Fiber Bubble Point (50:50 ethanol:water)	6.0 – 12.9 psig 0.41 – 0.89 barg	Each Unit
Regulatory Conformance		
Bio-safety		
This product has been tested by an independent laboratory and the results meet the specifications of the following tests:		
<ul style="list-style-type: none"> • Biological Reactivity Test, <i>In Vivo</i> per USP <88> Class VI • L929 MEM Elution Test – ISO 10993-5 (Cytotoxicity) • Hemolysis – Rabbit Blood (direct contact) – ISO 10993-4 		
Country of Origin: USA		
This product is manufactured in compliance with our ISO 9001 certified quality management system.		
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cytiva.com		

ATTACHMENT 3: ReadyCircuit™ label and Certificate of Quality example:

Old Label



New Label



New Certificate of Quality

Certificate of Quality		
Product: ReadyCircuit™ Assembly	Product Code or Catalog Number:	
Batch Number:	Product Description:	
Date of Manufacture:	Date of Expiration:	
Product Release Criteria		
The product above has met the following specifications established by Cytiva.		
Test/Characteristic	Specification	Frequency
ReadyCircuit		
CLEANLINESS Bacterial Endotoxin per USP <85>	<0.25 EU/ml	Daily Process Sample
INTEGRITY ReadyCircuit Bag	Pass	Each Device
STERILITY Validated sterile at an SAL of 10 ⁻⁶ according to AAMI TIR33:2005 and the principles of ISO/AAMI/ASTM 11137-1:2006.	Exposed to 27.5-40 kGy	Dosimetric Release
ULTA™ Capsule		
CLEANLINESS Bacterial Endotoxin per USP <85>	<0.25 EU/ml	Lot Sample
Conductivity	<1.3 µS/cm	Lot Sample
Total Organic Carbon	<500 ppb	Lot Sample
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Page 1 of 5	cytiva.com	DOC0771843 Rev BK

ATTACHMENT 4: ReadyToProcess™ Hollow Fiber Cartridge label and Certificate of Quality example:

Old Label



New Label



New Certificate of Quality

Certificate of Quality

Product: ReadyToProcess™ Hollow Fiber Cartridge
 Size 152,500 kD NMWC

Product Code Number: _____ **Product Catalog Number:** _____
Date of Manufacture: _____ **Date of Expiration:** _____
Batch Number: _____

Product Release Criteria

The product above has met the following specifications established by Cytiva.

Test/Characteristic	Specification	Frequency
HYDRAULIC TEST Clean Water Permeability @ 25°C	≥16 gfd/psig ≥399 LMH/barg	Batch Sample
INTEGRITY TEST Hollow Fiber Cartridge Fiber Air Diffusion (30 psig [2.1 barg] with water)	Pass ≤3 ml/min/ft ² ≤32.3 ml/min/m ²	Each Unit Each Unit
SELECTIVITY TEST Molecular Weight Marker Rejection	PVP K60 ≥40%	Membrane Lot Sample
CLEANLINESS – Hollow Fiber Cartridge Bacterial Endotoxin per USP <85> Conductivity Total Organic Carbon	<0.25 EU/ml <1.3 µS/cm <500 ppb	Process Sample Process Sample Process Sample

GAMMA IRRADIATION
 Dosimetric Release. Exposed to 27.5-40kGy.


Regulatory Conformance

Bio-safety
 This product has been manufactured with materials that comply with EMEA/410/01.
 This product meets the specifications of the following:

- Biological Reactivity Test, *In Vivo* per USP <98> Class VI
- 21CFR177 Indirect Food Additives
- L929 MEM Elution Test – ISO 10993-5 (Cytotoxicity)
- Hemolysis – Rabbit Blood (direct contact) – ISO 10993-4

**This product has been processed in an ISO 14644 Class 8 environment.
 This product is manufactured in compliance with our ISO 9001 certified quality management system.**

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 14 Walkup Drive
 Westborough, MA 01581 USA

cytiva.com 29318317 Rev AC

ATTACHMENT 5: WAVE™ cellbag™ label and Certificate of Quality example:

Old Label

CELLBAG™ DISPOSABLE BIOREACTOR

Part # CB0020L11-03 Rev AA

Volume 1 to 10 Liters

Lot # 17118142

Mfg Date 10 Apr 2020

Expires 10 Apr 2022

MADE IN USA



CB0020L11-03



17118142

Product Certification can be found at: www.gelifsciences.com/certificates




Bioclear™ 11 film
STERILE - FOR SINGLE USE
BIOPROCESSING USE ONLY
Pressure: 0.05 - 0.1 bar
Operating Temperature: 10°C-50°C

WAVE Bioreactor™
www.gelifsciences.com/wave

New Label

cytiva Cellbag™ Disposable Bioreactor

Part: CB0020L11-03 Rev AA

Volume: 1 to 10 Liters

Lot No.: 17118142

Mfg Date: 10APR2020

Expires: 10APR2022

Country of Origin: USA




1030000062

Product Certification can be found at: cytiva.com/certificates

Bioclear™ 11 film
STERILE - FOR SINGLE USE
BIOPROCESSING USE ONLY
Pressure: 0.05 - 0.1 bar
Operating Temperature: 10°C-50°C

WAVE™ Bioreactor
cytiva.com


New Certificate of Quality

Certificate of Quality		
Product: Disposable Bioreactor-Cellbag	Product Code Number:	
Lot Number:	Product Catalog Number:	
Date of Manufacture:	Revision:	
Expiration Date:		
Product Release Criteria		
The product above has been manufactured in a controlled environment and meets the following specifications established by Cytiva.		
Test/Characteristic	Specification	Frequency
VISUAL INSPECTION Product	Pass	100%
DIMENSIONAL INSPECTION Product	Pass	First and final article of each lot
INTEGRITY TEST Product	Pass	Each Unit
CLEANLINESS Endotoxin as determined using the Limulus Amebocyte Lysate (LAL) test	<0.125 EU/ml	Daily process sample
MICROBIOLOGICAL CONTROL Gamma Sterilization	27.5 - 40 kGy	Dosimetric Release
Regulatory Conformance		
Bio-safety Component materials in the fluid path were tested and met the criteria for the current USP Class VI Biological Test for Plastics.		
This product is manufactured in compliance with our ISO 9001 certified quality management system.		
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cytiva.com	DOC0791304 Rev AG	

ATTACHMENT 6: Xuri™ cellbag™ label and Certificate of Quality example:

Old Label

Xuri™ Cellbag™
Disposable Bioreactor




Part: 29105500 AC
Description: 20L Perf, pH, DO
Lot: 17119295
Serial No.: 1000333303
Mfg Date: 14Apr2020
Expires: 14Apr2022

Notes:

Meets USP <1043>. For Further Manufacturing Use only. Sterile.
Consult Xuri Bioreactor manual for use. Storage Temperature: 10°C-50°C
Xuri and Cellbag are trademarks of GE Healthcare companies.
GE Healthcare, 14 Walkup Drive, Westborough, MA 01581
www.gelifesciences.com/us/usa
pdl#rt: www.pdf.com/pdrt#rt

Made in USA

New Label




Xuri™ Cellbag™

Disposable Bioreactor

Part: 29279169 AC
Description: Xuri SP Cellbag 2L Perf
Lot No.: 12345678
Serial No.: 1000341619
Mfg Date: 08MAY2020
Expires: 08MAY2020

Notes:

Meets USP <1043>. For Further Manufacturing Use only. Sterile.
Consult Xuri Bioreactor manual for use. Storage Temperature: 10°C-50°C
cytiva.com



Global Life Sciences Solutions USA LLC
14 Walkup Drive
Westborough, MA 01581 USA
Country of Origin: USA

New Certificate of Quality

Certificate of Quality

Product:	Product Code Number:
Lot Number:	Product Catalog Number:
Date of Manufacture:	Expiration Date:

Product Release Criteria

The product above has been manufactured in a controlled environment and meets the following specifications established by Cytiva.

Test/Characteristic	Specification	Frequency
VISUAL INSPECTION Product	Pass	100%
DIMENSIONAL INSPECTION Product	Pass	First and final article of each lot
INTEGRITY TEST Product	Pass	Each Unit
CLEANLINESS Endotoxin as determined using the Limulus Amebocyte Lysate (LAL) test	<0.125 EU/ml	Daily process sample
MICROBIOLOGICAL CONTROL Gamma Sterilization	27.5 – 40 kGy	Dosimetric Release

Regulatory Conformance


Bio-safety
Cellbag film material was tested and meets the criteria for the current USP Class VI Biological Test for Plastics.

Suitability for onward manufacturing applications
This product complies with USP <1043> "ancillary materials for cell, gene, and tissue-engineered products", within the responsibilities applicable to the supplier. Other aspects of USP <1043> will be the responsibility of the end-user to assess. Cytiva cannot fulfill USP <1043> in regards to application and therapy specific aspects (e.g. use in finished therapeutic, assessment of removal from a finished therapeutic and possibly biocompatibility, cytotoxicity or adventitious agent testing).

For further information, including guidance on the set-up and use of this product, please refer to the Knowledge Center accessed through cytiva.com/celltherapy

This product is manufactured in compliance with our ISO 9001 certified quality management system.

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29112607 AC