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.

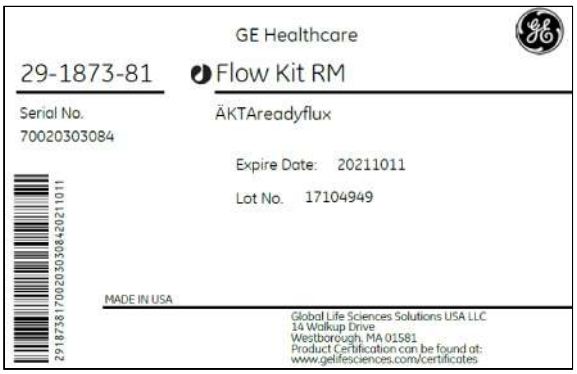
Yours sincerely,

Sarah Cote

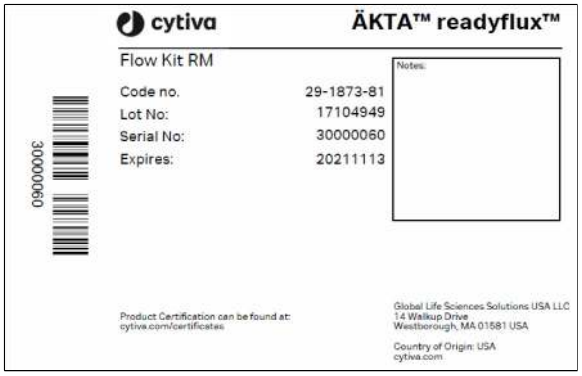
Sarah Cote
Regulatory Support Manager
Cytiva (formerly GE Healthcare Life Sciences)

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

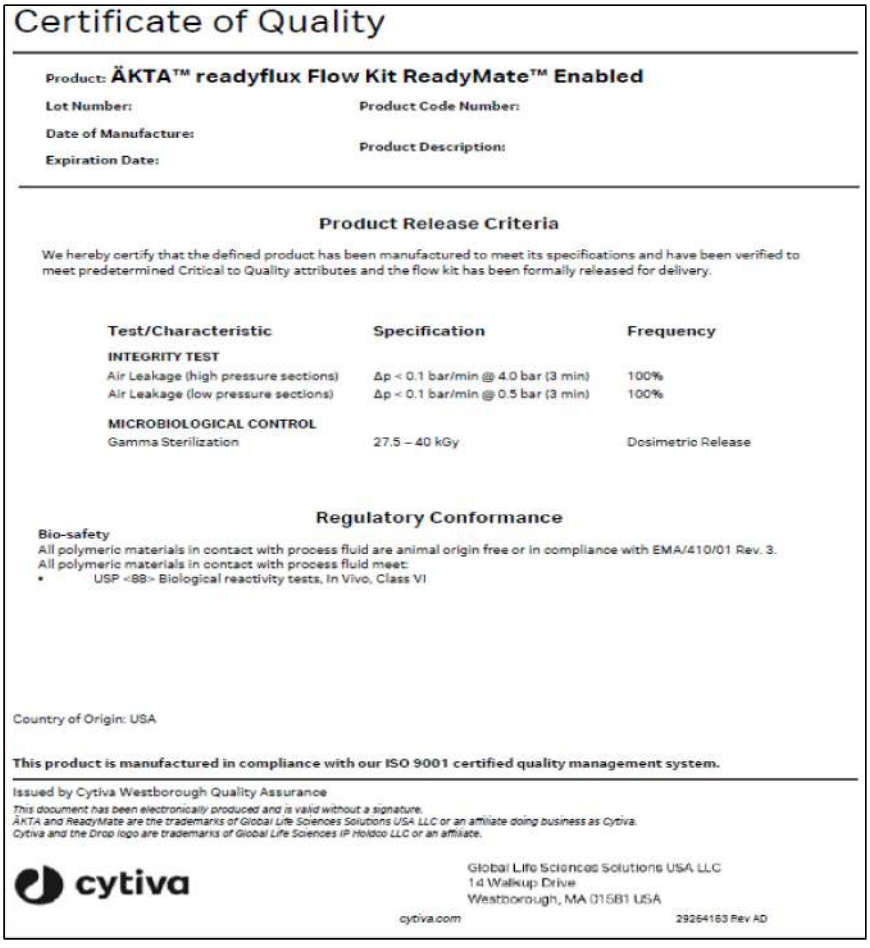
Old Label



New Label



New Certificate of Quality



Certificate of Quality

Product: ÄKTA™ readyflux Flow Kit ReadyMate™ Enabled

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

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)	Δp < 0.1 bar/min @ 4.0 bar (3 min)	100%
Air Leakage (low pressure sections)	Δp < 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

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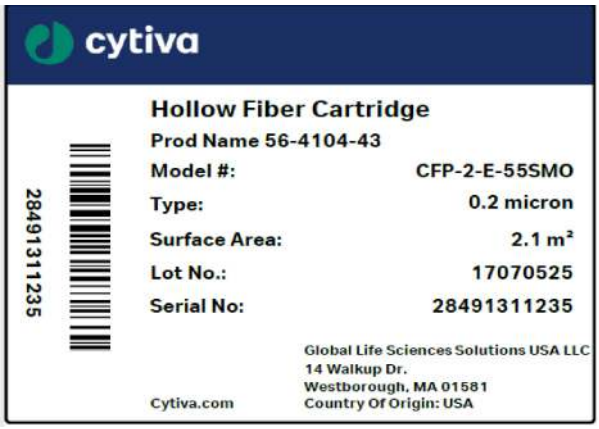
Global Life Sciences Solutions USA LLC
14 Walkup Drive
Westborough, MA 01581 USA

cytiva.com 29264163 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:

- Biological Reactivity Test, *In Vivo* 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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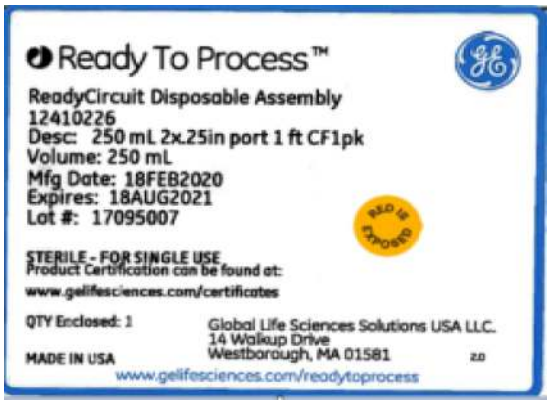
cytiva.com

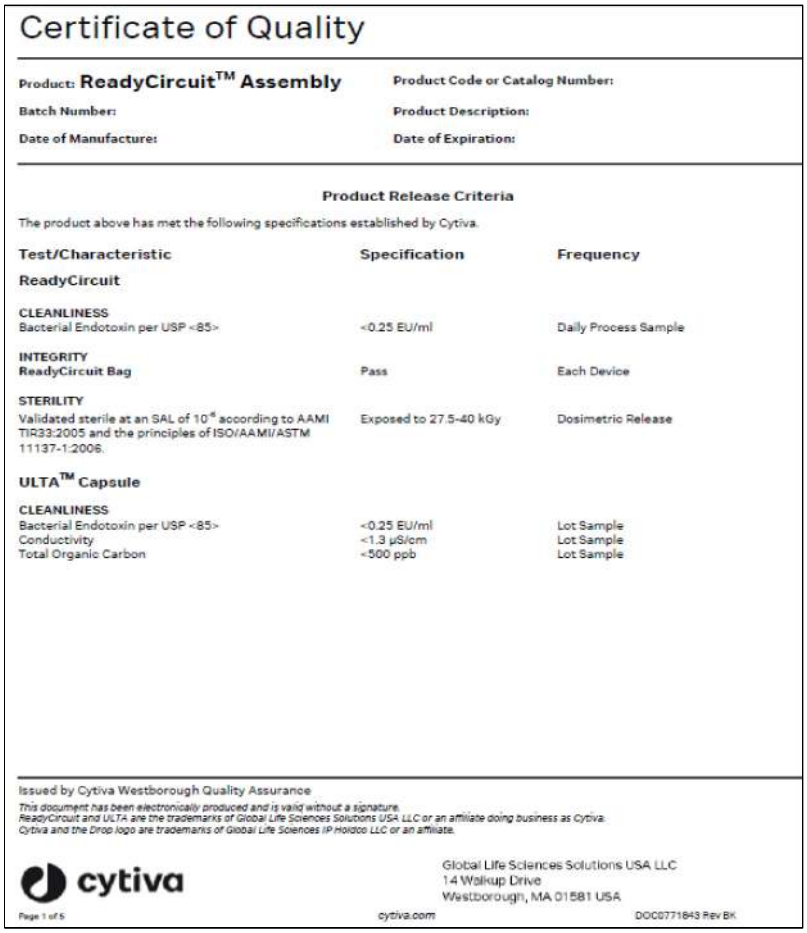
ATTACHMENT 3: ReadyCircuit™ label and Certificate of Quality example:

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> Conductivity Total Organic Carbon	<0.25 EU/ml <1.3 µS/cm <500 ppb	Lot Sample Lot Sample Lot Sample

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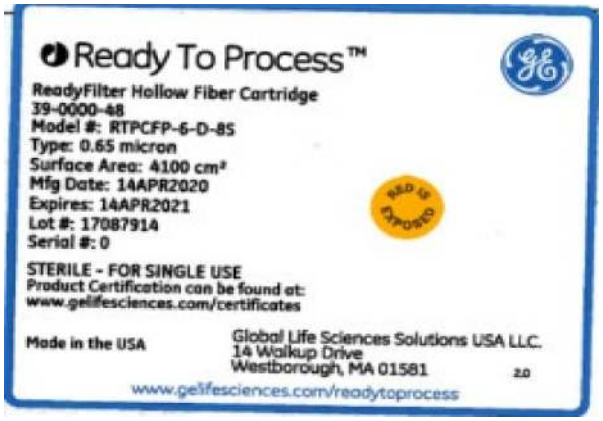
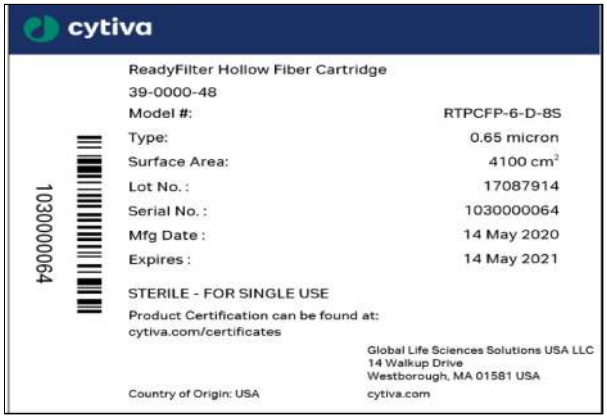
ATTACHMENT 4: ReadyToProcess™ Hollow Fiber Cartridge label and Certificate of Quality example:

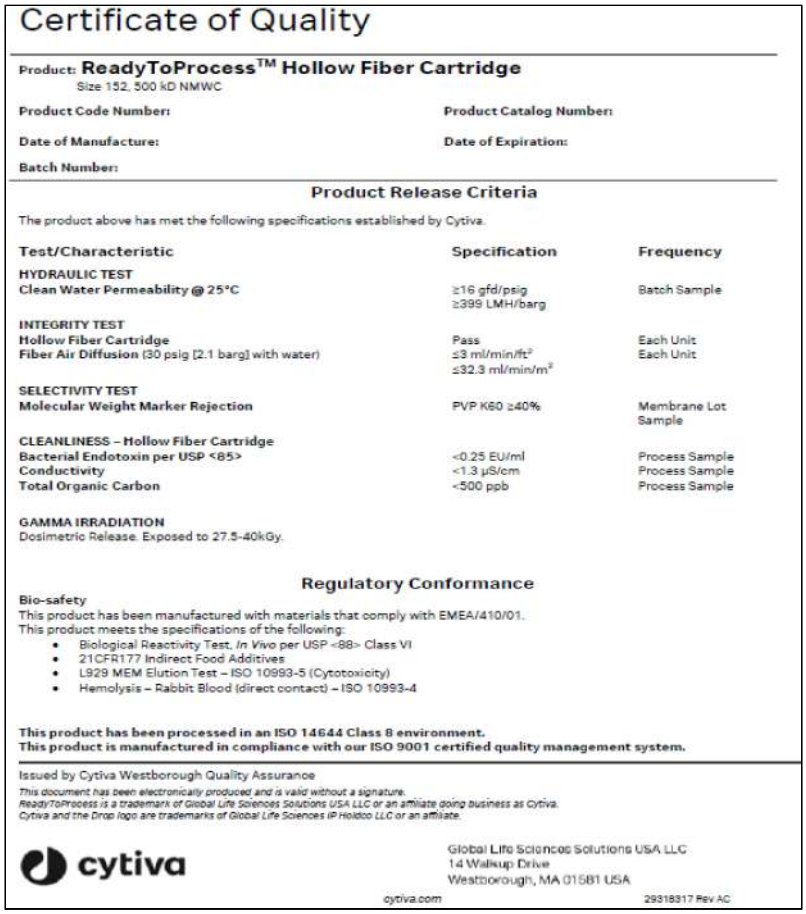
Old Label



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	Pass	Each Unit
Fiber Air Diffusion (30 psig [2.1 barg] with water)	≤3 ml/min/ft² ≤32.3 ml/min/m²	Each Unit
SELECTIVITY TEST		
Molecular Weight Marker Rejection	PVP K60 ≥40%	Membrane Lot Sample
CLEANLINESS – Hollow Fiber Cartridge		
Bacterial Endotoxin per USP <85>	<0.25 EU/ml	Process Sample
Conductivity	<1.3 µS/cm	Process Sample
Total Organic Carbon	<500 ppb	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 <88> 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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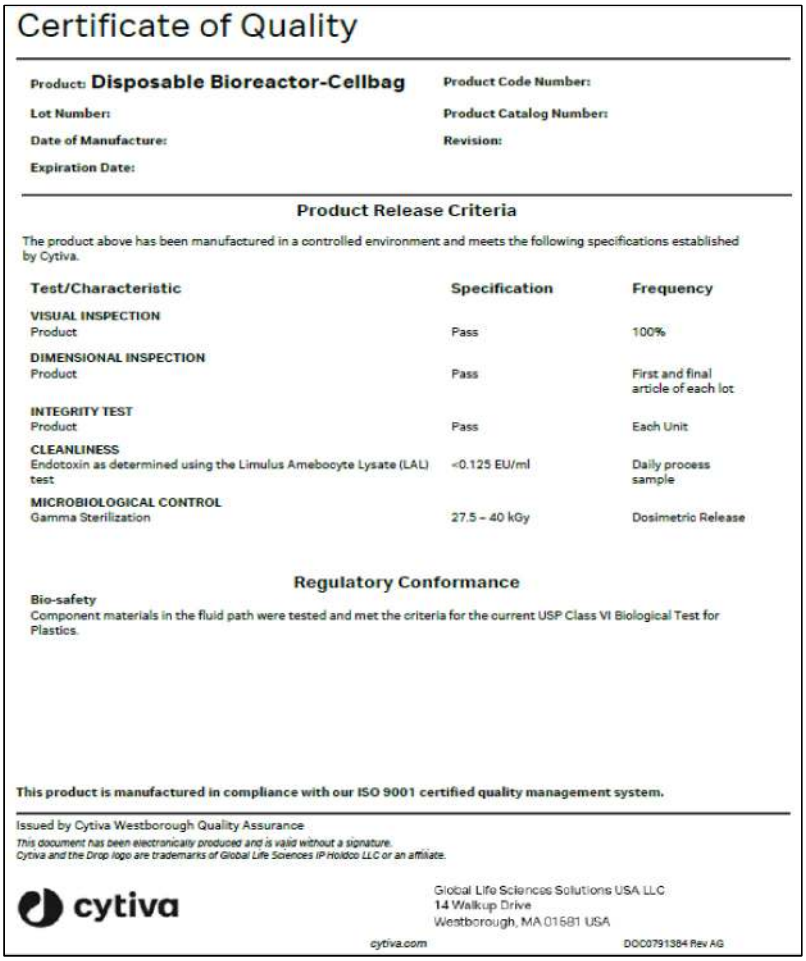
cytiva.com 29318317 Rev AC

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

Old Label

New Label

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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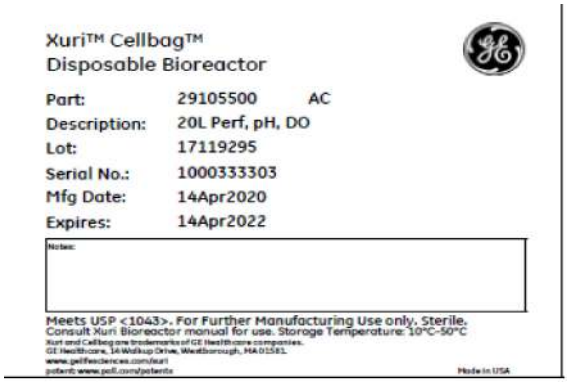
cytiva.com DOC0791384 Rev AG

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/xuri
patents: www.ge.com/patents
Made in USA

New Label


cytiva Xuri™ Cellbag™

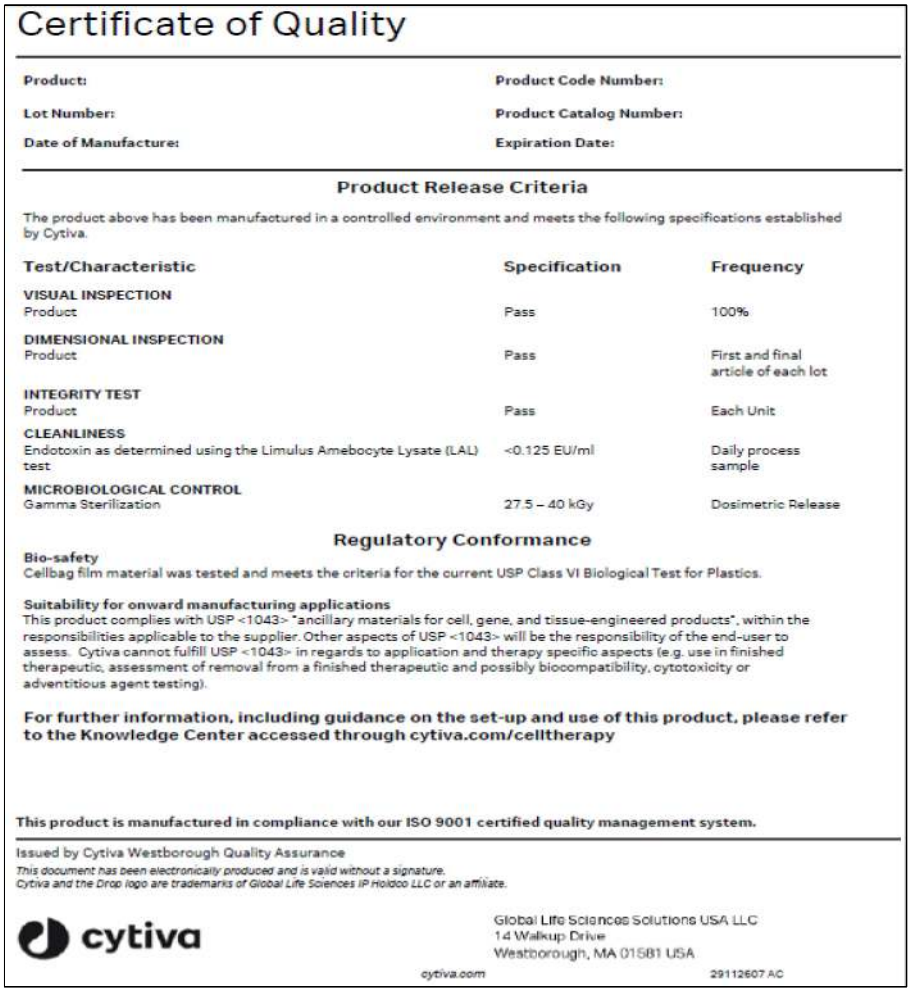
Disposable Bioreactor

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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14 Walkup Drive
Westborough, MA 01581 USA

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