Cytiva
Björkgatan 30
75184 Uppsala
Sweden

Change Control Notification - Update

Uppsala, Sweden, 1 April, 2020 TW392538

Regarding: GE Healthcare Life Sciences (Biopharma business) is now Cytiva

Dear Customer,

As part of our change control program, we write to notify you that Danaher Corporation's purchase of the GE Healthcare Life Sciences Biopharma business units consisting of BioProcess, Cell & Gene Therapy and Genomics & Cellular Research is now complete. Starting today, we will do business as Cytiva.

Cytiva is now part of the Danaher Corporation, which is a public company.

In scope products

The products in scope of this notification include all GE Healthcare Life Sciences Biopharma business products including all products for which change control notifications are provided by the Regulatory Support web page. Some examples of the Cytiva brand names are ÄKTA, Asymptote, AxiChrom, Biacore, Biosafe, Capto, FlexFactory, HyClone, KUBio, MabSelect, ReadyToProcess, Sefia, Sepax, Sepharose, UNICORN, WAVE, Whatman, Xcellerex, and Xuri.

What is not changing

This is a change of the company brand name and legal entity names only. There is no change to the products. Please be assured that we will continue to deliver our products and services to you as usual. The following main items WILL NOT CHANGE at this time as a result of the transition steps:

- Our quality management system
- Processes for change control including change control notifications
- Manufacturing processes
- Manufacturing locations
- Equipment used in the manufacturing of our products
- Products, product specifications and drawings as such will not change even though brand name and/or logo will get updated
- Product names
- Product part/code numbers
- Lot numbering system
- Quality release claims
- Terms of legal agreements will remain in effect according to their respective terms
- Your account teams and contacts

Product documentation provided under the company name GE Healthcare Life Sciences including User manuals and instructions, Specifications, Statements, Regulatory Support Files, Validation Guides, Validations Support Files, Hardware Product Documentation (ToP) and Vendor questionnaires REMAIN VALID.

What is changing

Company Brand changes

- The company brand name Cytiva will gradually be included in labelling and/or other product documentation such as certificates, user documentation etc. This means that the GE brand will be removed or replaced on our products and product documentation over time. The changes in label and product documentation imply no difference in product quality or performance. Product quality release claims remain unchanged.

Re-branding

- Labels and certificates will be updated with the Cytiva name including logo, legal entity name and legal entity address (where applicable) over time. If additional changes are introduced at the same time, these changes will be communicated in a separate change control notification for the affected product category. Examples of updated certificates and labels will be provided in additional forthcoming change control notifications. In addition, updated certificates and label examples will be published at www.gelifesciences.com/4customers. See attached examples of current labels and certificates where planned changes to branding and legal entity are marked.
- Technical drawings will be updated with new brand name at the time they are being revised for other reasons.
- Packaging material where the GE brand and logo is displayed will be updated over time to either include the Cytiva brand and logo or remove the GE company name and logo.

Mixed branding

- 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. For products with a longer shelf life (>2 years) the transition phase can last for several years.
- 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 and legal entity details 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.

Web and email addresses

Our new web address will be cytiva.com and our new email addresses will be firstname.lastname@cytiva.com. For a limited period of time, our old email addresses will be forwarded to our new address, please update your contacts accordingly.

ISO certificate update

Our ISO 9001-2015 certificate (#456061-02) will be updated to reflect the change in company name. The updated ISO certificate will be available on request and online.

Legal Entity updates

Legal entity changes referenced in Table 1 became effective at deal close (31 March 2020). In Table 2 the legal entity names will remain the same until several months after deal close (31 March 2020). The exact date will be communicated via change control notification prior to the change. For more information regarding legal entity changes please visit www.gelifesciences.com/4customers.

Table 1: Legal Entity changes at deal close

Region	Current Legal Entity	New Legal Entity	Impacts labels and product documentation (Y/N)	Effective from (date)
Canada	GE Healthcare Bio-Sciences Company (Canada)	Global Life Sciences Solutions Canada ULC	N	31 Mar 2020
Germany	GE Deutschland Holding GmbH	Global Life Sciences Solutions Germany GmbH	N*	31 Mar 2020
Poland	GE Medical Systems Polska Sp. z.o.o.	Global Life Sciences Solutions Poland Sp. z o.o	N	31 Mar 2020
Taiwan	GE Medical Systems Taiwan Limited	Pall Singapore Taiwan Branch Holding Company Pte. Ltd.	N	31 Mar 2020
Turkey	GE Medical Systems Turkiye Limited Sirketi	Beckman Coulter Biyomedikal Ürünler Sanayi Ve Ticaret Limited Şirketi	N	31 Mar 2020
UK	GE Healthcare UK Limited	Global Life Sciences Solutions Operations UK Ltd	Y*	31 Mar 2020
UK	GE Healthcare Ltd	Global Life Sciences Solutions Manufacturing UK Ltd	N*	31 Mar 2020

*) Regarding the legal entity name used on product labeling and documentation, regulations allow for the use of a Manufacturing Legal Entity or a Distribution (Sales) Legal Entity. Most manufacturing sites use their Manufacturing

Legal Entity details on product labels and documentation. However, there are some exceptions: Whatman products produced in China (Tonglu), UK (Cardiff) and Germany (Dassel) use the UK Sales Legal Entity name (Global Life Sciences Solutions Operations UK Ltd) on their product labels and documentation.

Table 2. Legal entity and branch name changes occurring in the coming months (details to follow)

Region	Current Legal Entity	New Legal Entity	Impacts labels and product documentation (Y/N)	Effective from (date)
Argentina	GE Healthcare Life Sciences Argentina SA	To be announced	N	To be announced
Brazil	GE Healthcare Life Sciences do Brasil	To be announced	N	To be announced
Sweden	GE Healthcare Bio-Sciences AB	To be announced	Y	To be announced
China	GE Biotechnology (Hangzhou) Co., Ltd.	To be announced	Y	To be announced
Europe	GE Healthcare Europe GmbH (+13 European local branches)	To be announced	N	To be announced
GE Healthcare Europe GMBH (Germany) is the main Legal Entity for Europe and has the following local branches:				
Austria Export	GE Healthcare Europe Gmbh Vienna International Branch	To be announced	N	To be announced
Austria	GE Healthcare Europe GmbH, Zweigniederlassung Österreich	To be announced	N	To be announced
Belgium	GE Healthcare Europe GmbH, Branch Belgium	To be announced	N	To be announced
Denmark	GE Healthcare, Filial Af GE Healthcare Europe GmbH, Tyskland	To be announced	N	To be announced
Finland	GE Healthcare Europe GmbH Suomen sivuliike (filial Finland)	To be announced	N	To be announced

Region	Current Legal Entity	New Legal Entity	Impacts labels and product documentation (Y/N)	Effective from (date)
France	GE Healthcare Europe GmbH, succursale France	To be announced	N	To be announced
Italy	GE Healthcare Europe GmbH filiale Italiana	To be announced	N	To be announced
Netherlands	GE Healthcare Europe GmbH, Branch Netherlands	To be announced	N	To be announced
Norway	GE Healthcare Europe GmbH, filial Norge	To be announced	N	To be announced
Portugal	GE Healthcare Europe GmbH, sucursal em Portugal	To be announced	N	To be announced
Spain	GE Healthcare Europe GmbH, Sucursal en Espana	To be announced	N	To be announced
Sweden	GE Healthcare Europe GmbH Tyskland Filial Sverige	To be announced	N	To be announced
Switzerland	GE Healthcare Europe GmbH, Zweigniederlassung Schweiz	To be announced	N	To be announced

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.gelifesciences.com/4customers (changing soon to www.cytiva.com/4customers).

Planned forthcoming change notifications:

- Legal entity changes as listed in Table 2.

Attachment

- Label and certificate examples. Company brand marked with red box will be updated to Cytiva brand, legal entity marked with green box was updated 31 Sep. 2019 and legal entity marked with blue box will be updated (date to be announced).

To receive future notifications about our products, please register and subscribe for change control notifications at our website: www.gelifesciences.com/rsf (changing to www.cytiva.com/rsf) We recommend the use of business-related e-mail addresses instead of personal e-mail addresses, ensuring better information sustainability (example: supplier.notifications@company.com).

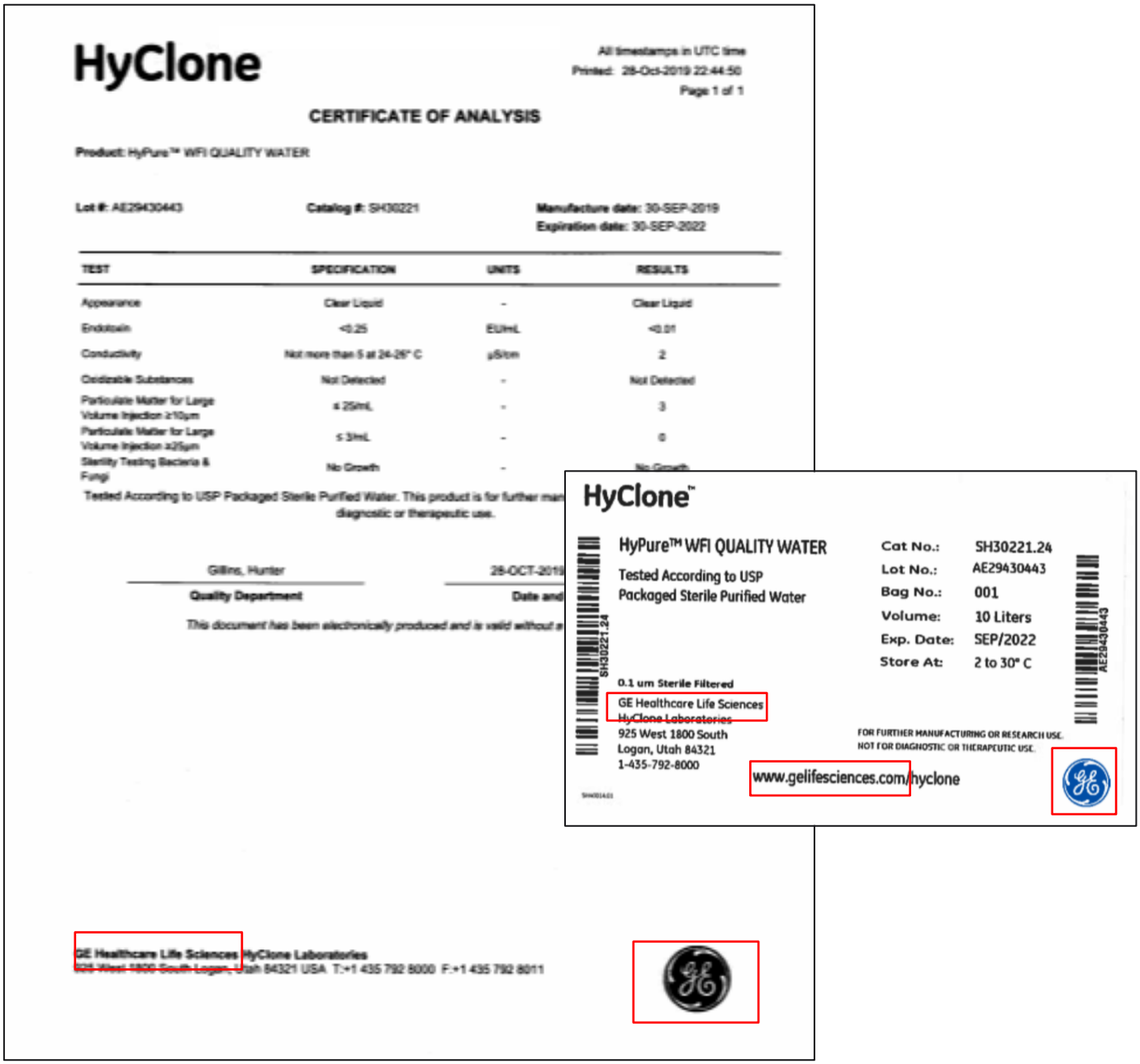
While your organization is assessing the potential impact of these changes, please do not hesitate to contact your regional sales office or us at RegulatorySupportPS@ge.com (changing to RegulatorySupport@cytiva.com).

Yours sincerely,

Liz Samuelsson

Sr. Customer Regulatory Support Manager

Certificate and label example: Company brand marked with red box will be updated to Cytiva brand.



HyClone

All timestamps in UTC time
Printed: 28-Oct-2019 22:44:50
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CERTIFICATE OF ANALYSIS

Product: HyPure™ WFI QUALITY WATER

Lot #: AE29430443 Catalog #: SH30221 Manufacture date: 30-SEP-2019
Expiration date: 30-SEP-2022

TEST	SPECIFICATION	UNITS	RESULTS
Appearance	Clear Liquid	-	Clear Liquid
Endotoxin	<0.25	EU/mL	<0.01
Conductivity	Not more than 5 at 24-26° C	µS/cm	2
Oxidizable Substances	Not Detected	-	Not Detected
Particulate Matter for Large Volume Injection ≥10µm	≤ 25/mL	-	3
Particulate Matter for Large Volume Injection ≥25µm	≤ 3/mL	-	0
Sterility Testing Bacteria & Fungi	No Growth	-	No Growth

Tested According to USP Packaged Sterile Purified Water. This product is for further man
diagnostic or therapeutic use.

Gillins, Hunter — Quality Department
28-OCT-2019 — Date and

This document has been electronically produced and is valid without a

GE Healthcare Life Sciences HyClone Laboratories
925 West 1800 South Logan, Utah 84321 USA T:+1 435 792 8000 F:+1 435 792 8011

HyClone™

HyPure™ WFI QUALITY WATER
Tested According to USP
Packaged Sterile Purified Water

Cat No.: SH30221.24
Lot No.: AE29430443
Bag No.: 001
Volume: 10 Liters
Exp. Date: SEP/2022
Store At: 2 to 30° C

SH30221.24
AE29430443

0.1 um Sterile Filtered
GE Healthcare Life Sciences
HyClone Laboratories
925 West 1800 South
Logan, Utah 84321
1-435-792-8000

FOR FURTHER MANUFACTURING OR RESEARCH USE.
NOT FOR DIAGNOSTIC OR THERAPEUTIC USE.

www.gelifesciences.com/hyclone

Certificate and label example: Company brand name marked with red box will be updated to Cytiva brand
legal entity marked with green box was updated 31 Sep. 2019

GE Healthcare

Certificate of Quality

Product: **ReadyToProcess™ Hollow Fiber Cartridge**
Size 4M-65, 10 kD NMWC

Product Code Number: 39-0000-74
Product Catalog Number: RTPUFP-10-C-5S
Date of Manufacture: 23JAN2020
Date of Expiration: 23JAN2021
Batch Number: 17083248

Product Release Criteria

The product above has met the following specifications established by GE Healthcare.

Test/Characteristic	Specification	Frequency
HYDRAULIC TEST Clean Water Permeability @ 25°C	≥2.5 gfd/psig ≥62.4 LMH/barg	
INTEGRITY TEST Hollow Fiber Cartridge Fiber Air Diffusion (30 psig [2.1 barg] with water)	Pass ≤3 ml/min/ft² ≤32.3 ml/min/m²	
SELECTIVITY TEST Molecular Weight Marker Rejection	PVP K15 ≥65%	
CLEANLINESS – Hollow Fiber Cartridge Bacterial Endotoxin per USP <85> Conductivity Total Organic Carbon	<0.25 EU/ml <1.3 µS/cm <500 ppb	
STERILITY Validated sterile at an SAL of 10^{-6} according to AAMI TIR33:2005 and the principles of ISO/AAMI/A		

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.

Issued by GE Healthcare Westborough Quality Assurance
This document has been electronically produced and is valid without a signature.

imagination at work

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

Ready To Process™

ReadyFilter Hollow Fiber Cartridge
39-0000-74
Model #: RTPUFP-10-C-5S
Type: 10,000 NMWC
Surface Area: 2000 cm²
Mfg Date: 23JAN2020
Expires: 23JAN2021
Lot #: 17083248
Serial #: 0

RED IS EXPOSED

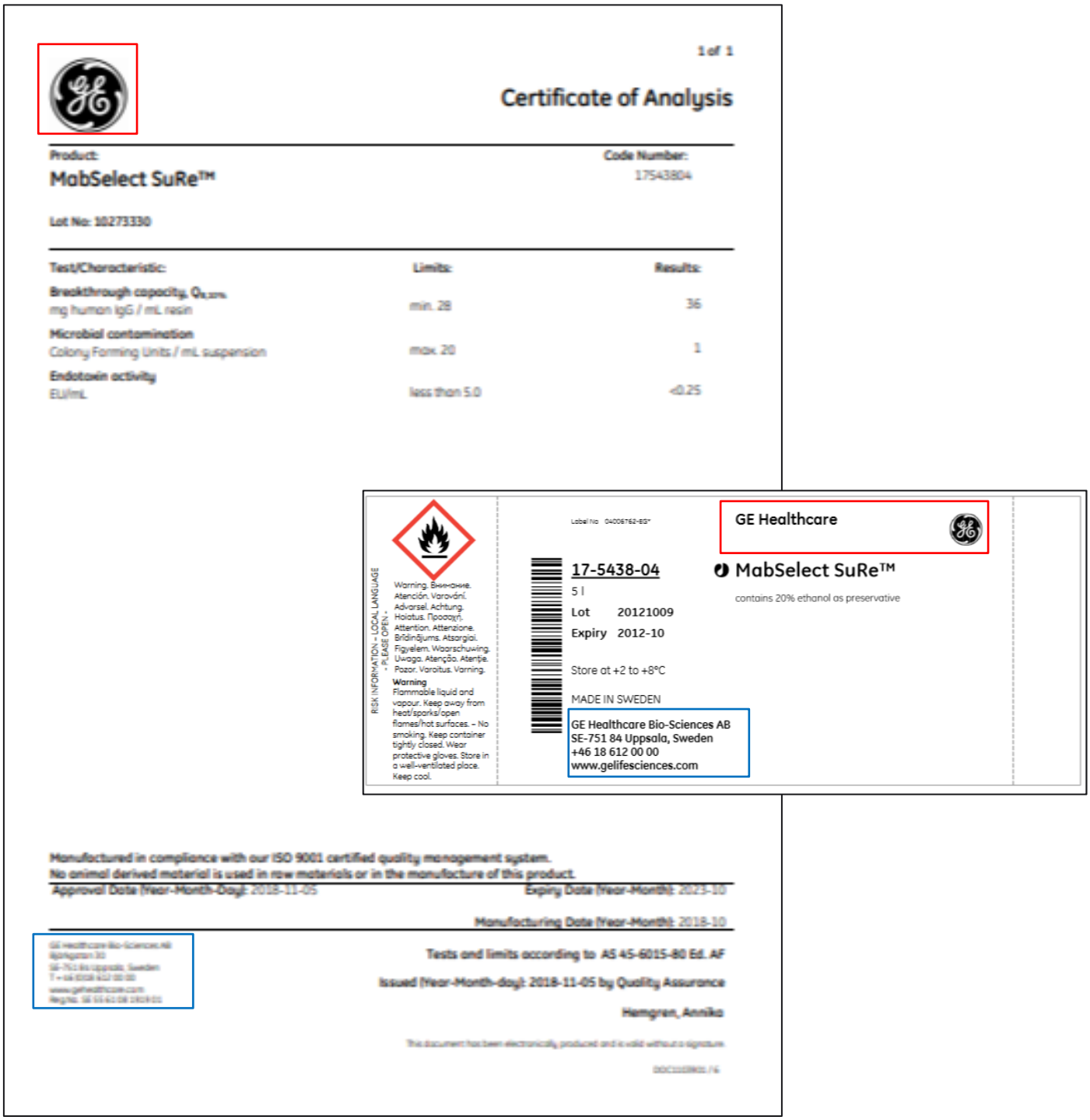
STERILE – FOR SINGLE USE
Product Certification can be found at:
www.gelifesciences.com/certificates

Made in the USA

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

www.gelifesciences.com/readytoprocess

Certificate and label example: company brand marked with red box will be updated to Cytiva brand, legal entity marked with blue box will be updated to new legal entity. Date for the change to be announced.



1 of 1

Certificate of Analysis

Product: MabSelect SuRe™

Code Number: 17543804

Lot No: 10273330

Test/Characteristic:	Limits:	Results:
Breakthrough capacity, $Q_{b\ 10\%}$ mg human IgG / mL resin	min. 28	36
Microbial contamination Colony Forming Units / mL suspension	max. 20	1
Endotoxin activity EU/mL	less than 5.0	<0.25

RISK INFORMATION – LOCAL LANGUAGE – PLEASE OPEN –

Warning. Внимание. Atención. Varování. Advarsel. Achtung. Hoiatus. Προσοχή. Attention. Attenzione. Brīdinājums. Atsargiai. Figyelem. Waarschuwing. Uwaga. Atenção. Atenție. Pozor. Varoitus. Varning.

Warning
Flammable liquid and vapour. Keep away from heat/sparks/open flames/hot surfaces. – No smoking. Keep container tightly closed. Wear protective gloves. Store in a well-ventilated place. Keep cool.

Label No 04006762-60*

GE Healthcare

17-5438-04
5 l
Lot 20121009
Expiry 2012-10

Store at +2 to +8°C

MADE IN SWEDEN

GE Healthcare Bio-Sciences AB
SE-751 84 Uppsala, Sweden
+46 18 612 00 00
www.gelifesciences.com

MabSelect SuRe™
contains 20% ethanol as preservative

Manufactured in compliance with our ISO 9001 certified quality management system.
No animal derived material is used in raw materials or in the manufacture of this product.

Approval Date (Year-Month-Day): 2018-11-05

Expiry Date (Year-Month): 2023-10

Manufacturing Date (Year-Month): 2018-10

Tests and limits according to AS 45-6015-80 Ed. AF

Issued (Year-Month-day): 2018-11-05 **by Quality Assurance**

Hemgren, Annika