

Cytiva Björkgatan 30 75184 Uppsala Sweden

Change Control Notification

Uppsala, Sweden 09 June, 2020

TW401922, 401923

Regarding: Label, Certificate of Analysis and Analytical Specification update

Dear Customer,

As part of our change control program, we write to notify you of changes to labels, Certificate of Analysis and analytical specifications for the below mentioned affected products.

Affected products

The products in scope of this notification include chromatography resins, ReadyToProcess™ columns, prefilled columns, density gradient media, microcarriers and Biacore™ consumables, manufactured in Uppsala Sweden.

Change description

Labels and Certificate of Analysis are updated with the Cytiva name including logo and legal entity name. Examples of updated certificates and labels are included with this notification. The following changes are introduced:

- Change of legal entity name from GE Healthcare Bio-Sciences AB to Cytiva Sweden AB
- Change of company brand name and logo
- To align the presentation of code numbers on labels and Certificate of Analysis, code numbers on labels are now written without dashes in the same way as on Certificate of Analysis.
- Numbering of test/characteristics on Certificate of Analysis is removed (when not already implemented in earlier updates)
- Minor editorial changes (e.g. ml changed to mL)

Analytical specifications for affected products will be updated to next edition with corresponding changes.

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, legal entity name over time. 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.

Implementation of change

The new legal entity name is valid from 15 June 2020 and is introduced for material labeled and/or released from this date forward.

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 <u>www.cytiva.com/4customers</u>.

Attachment

- Label and certificate examples

To receive future notifications about our products, please register and subscribe for change control notifications at our website: 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 Customer Service team or us at <u>RegulatorySupport@cytiva.com</u>.

Yours sincerely,

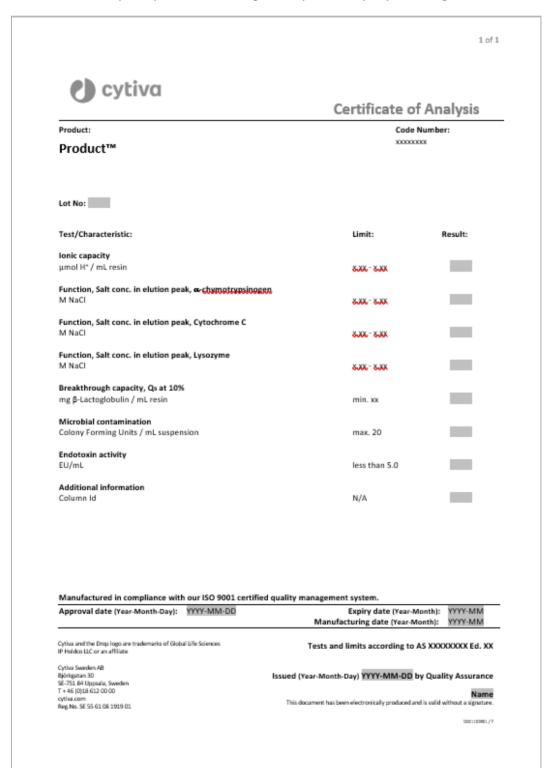
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Liz Samuelsson

Sr. Customer Regulatory Support Manager

Attachment

Certificate of Analysis layout with new legal entity and company branding



Example of label with current and new legal entity and company branding





