Change Notification
CC-21-0143

Revision of Certificates of Origin and TSE-/BSE statements

Affected product groups:
All MACS® GMP Products, including all Reagents, Media and Cell Culture bags
All ClinMACS® Reagents – all variants
All ClinMACS Tubing Sets, ClinMACS Prodigy Tubing Sets and Accessories
ClinMACS PBS/EDTA Buffer – all variants
All CryoMACS® Freezing Products
MACS ART Annexin V – all variants

Category of change: Change of certificates

Current State: Either a Certificate of Origin (CoO) or a TSE-/BSE statement is available for all clinical products.

Following is applicable for statements in the current valid versions:
1. If it is stated, that a product comes into contact with animal or human materials during manufacture, the specific source is not listed.
2. There is no designated field for a ‘final filled’ lot number, if required.
3. Following statement is mentioned on the bottom of each TSE-/BSE statement and CoO: “The information provided in this document is given to the best of our knowledge and belief, and is based on the information available at the time of this document was issued.”

Planned change: A general update of the Certificates of Origin and TSE-/BSE statements will be performed.

Thereby the following will be included:
1. If a product comes into contact with materials of animal and/or human origin during manufacture, source of materials will be stated.
2. A designated field for entering the ‘final filled’ lot number will be added in the upper part of the template, if required.
3. The statement on the bottom of each TSE-/BSE statement and CoO will be updated as follows: “The information provided in this document is given to the best of our knowledge and belief, and is valid until a product formulation is changed or the product is discontinued. Changes in this document will be communicated by change notifications.”
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**Justification/Evaluation:** This update of certificates and statements will increase customer satisfaction by addition of further information and harmonization of templates.

There is no change of raw material or manufacturing process. Therefore no impact on the performance, quality and safety of the affected product could be identified.

**Estimated Implementation** Q4/2021

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

p.p. 06 May 2021
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG