# Change Notification

**CC-21-0020**

## Change of sterile labeling TexMACS™ GMP Medium

<table>
<thead>
<tr>
<th>Product</th>
<th>Material No.</th>
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<tbody>
<tr>
<td>TexMACS GMP Medium, 2000 mL bag</td>
<td>170-076-306</td>
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</table>

**Category of change:** Change of labeling

**Current State:** TexMACS GMP Medium is labeled “0.1 µm filtered”. It is tested for sterility in accordance with Ph.Eur. chapter 2.6.1.

The package insert of TexMACS GMP Medium includes different product formats:
- 170-076-306 TexMACS GMP Medium 2000 mL bag,
- 170-076-307 TexMACS GMP Medium 1000 mL bottle and
- 170-076-309 TexMACS GMP Medium 1000 mL bottle (Phenol Red)

**Planned change:** TexMACS GMP Medium 2000 mL bag (170-076-306) will be labeled “Sterile” additionally.

The current layout of the product label remains unaffected. The word "Sterile" will be added.

The current package inserts will be divided into two separate documents. TexMACS Medium in bag (170-076-306) and TexMACS in bottle format (170-076-307, 170-076-309) get separate product information.

**Justification/Evaluation:** In order to facilitate the assessment of possible sterility risks when used in phase III clinical trials or commercial manufacturing, the bag filling process for TexMACS GMP Medium, 2000 mL bag (170-076-306), was reevaluated.

Possible non-sterility risks for the bag filling process of TexMACS GMP Medium were analyzed, evaluated, and actions to reduce the corresponding risks were defined.

Various validations were initiated and carried out for the implementation of sterile labeling of TexMACS GMP Medium, 2000 mL bag. All process validation steps have been completed and meet the requirements for sterile labeling.

As a consequence, TexMACS GMP Medium, 2000 mL bag can be labeled "Sterile".

There is no change of raw material or products themselves. Changes have been assessed and no impact on the performance, quality and safety of the affected products could be identified.
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Estimated Implementation

Q3/2021

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

07.May.2021

Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG