Change Notification
CC-21-0022

Adaption of REF number of CliniMACS® Tubing Sets

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory status</th>
<th>REF No. GMP product</th>
<th>REF No. RUO product</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS Tubing Set</td>
<td>GMP</td>
<td>170-076-650</td>
<td>165-01</td>
</tr>
<tr>
<td>CliniMACS Tubing Set LS</td>
<td>GMP</td>
<td>170-076-651</td>
<td>168-01</td>
</tr>
<tr>
<td>CliniMACS Depletion Tubing Set</td>
<td>GMP</td>
<td>170-076-652</td>
<td>266-01</td>
</tr>
</tbody>
</table>

Category of change: Adaption of the reference number

Current State: The CliniMACS Tubing Sets GMP have been or will be introduced the first time to market as a replacement of the Research Use Only (RUO) product versions. The CliniMACS Tubing Set (GMP) and CliniMACS Tubing Set LS (GMP) have been released in February 2021 and the CliniMACS Depletion Tubing Set (GMP) is planned to be released in April 2021. The current product and carton label of the GMP sets contains the 9 digit REF number, CliniMACS logo, and a watermark.

Planned change: The product and carton labels of the new GMP CliniMACS tubing sets will be adapted showing the 5 digit REF number of the discontinued RUO CliniMACS Tubing Sets in addition to the actual 9 digit REF number. As the Software of the CliniMACS Plus Instrument does not recognize the new REF number of the GMP CliniMACS tubing sets, the old numbers are still valid. Also, the layout of the label will be changed.

Justification/Evaluation: The addition of the 5-digit REF number on the packaging label allows the correct selection of the respective CliniMACS tubing set for its application on the CliniMACS Plus Instrument. The introduction of the new label layout drives towards achieving an effective label harmonization. The intended purpose of the affected CliniMACS tubing sets remains unchanged.

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

Estimated implementation: Q2/2021

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

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

01.Mar.2021