## Change Notification

**CC-21-0089**

### Revision of package inserts of CliniMACS® Reagents, Biotin Conjugates and CliniMACS Buffer

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Status</th>
<th>Order No / REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS PBS/EDTA Buffer 1000mL</td>
<td>CE</td>
<td>200-070-025 / 700-25</td>
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<tr>
<td>CliniMACS PBS/EDTA Buffer 2 x 3L</td>
<td>CE</td>
<td>200-070-029 / 700-29</td>
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<tr>
<td>CliniMACS CD34 Reagent</td>
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<td>200-070-100 / 171-01</td>
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<td>CliniMACS CD1c (BDCA-1)-Biotin</td>
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<td>200-070-114 / 277-01</td>
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<td>CliniMACS CD25 Reagent</td>
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<td>200-070-131 / 274-01</td>
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<tr>
<td>CliniMACS TCRalpha/beta-Biotin</td>
<td>CE</td>
<td>200-070-148 / 701-48</td>
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<tr>
<td>CliniMACS Anti-Biotin Reagent</td>
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<td>200-070-120 / 173-01</td>
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<tr>
<td>CliniMACS Cytokine Capture System (IFN-gamma)</td>
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<td>200-070-111 / 279-01</td>
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<tr>
<td>CliniMACS CD304 (BDCA-4) Reagent</td>
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<td>CliniMACS CD14 Reagent</td>
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<td>200-070-118 / 272-01</td>
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<td>CliniMACS CD4 Reagent</td>
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<td>200-070-115 / 275-01</td>
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<td>CliniMACS CD45RA Reagent</td>
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<td>CliniMACS CD45RA Reagent XS</td>
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<td>CliniMACS CD34 Reagent</td>
<td>Australia</td>
<td>200-070-270 / 171-01</td>
</tr>
</tbody>
</table>

**Category of change:** Change of package insert

**Current State:** A package insert is in place for all above mentioned CliniMACS Reagents, Biotin Conjugates and CliniMACS Buffer.

**Planned change:** According to increased regulatory requirements due to the Medical Device Regulation (MDR), package inserts of affected CliniMACS Reagents, Biotin Conjugates and CliniMACS PBS/EDTA Buffer need to be adapted as follows:

1. Addition of section Contraindications: “The *product name* has no contraindication.”
2. Addition in section Further information: “The summary of safety and clinical performance for this product is provided by Miltenyi Biotec B.V. & Co. KG for Publishing on the public website of the European database on medical devices (Eudamed).”
3. Additionally for package insert of CliniMACS CD34 Reagent (Australia): deletion of CliniMACS Logo and change of layout and color specification.
Revision of package inserts of CliniMACS® Reagents, Biotin Conjugates and CliniMACS Buffer

**Justification/Evaluation:**

There is an update of package inserts to fulfil requirements of MDR.

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**

Q3/2022

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

21.Feb.2022

Manager QA Audit/Customer/Supplier

Miltenyi Biotec B.V. & Co.KG