
<table>
<thead>
<tr>
<th>Product</th>
<th>Material No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS Prodigy EP-2</td>
<td>170-076-623</td>
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<tr>
<td>CliniMACS Prodigy EP-4</td>
<td>170-076-624</td>
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</tbody>
</table>

**Category of change:** Change of packaging

**Current State:** The above mentioned CliniMACS Prodigy EP-2 and CliniMACS Prodigy EP-4 (further EP-x) are packed into a Tyvek bag as primary packaging. This Tyvek bag serves as sterile barrier. The CliniMACS Prodigy EP-x are arranged in the Tyvek bag according to a defined procedure.

**Planned change:** Additional packaging components (carrier foils) will be introduced for an easier installation of the CliniMACS Prodigy EP-x onto the CliniMACS Electroporator. The existing Tyvek Bag will be replaced by a larger Tyvek bag. The arrangement of the components in the bag will be slightly changed.

**Justification/Evaluation:** 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:** Q3/2021

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

05 May 2021