Adaption of labelling material of CliniMACS Prodigy® TS 521

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Status</th>
<th>Material No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS Prodigy TS 521</td>
<td>CR</td>
<td>200-073-618</td>
</tr>
<tr>
<td>CliniMACS Prodigy TS 521</td>
<td>MACS GMP</td>
<td>170-076-616</td>
</tr>
</tbody>
</table>

**Category of change:** Change of labelling

**Current State:** A product label, carton label, installation aid, and package insert are available for the CliniMACS Prodigy TS 521.

**Planned change:** Following general adaptions will be performed:
- Removal of Information regarding US telephone number
- Addition of symbol for Storage in vapor phase of liquid nitrogen.

Additional adaptions of the package insert will be performed:
- Addition of precaution regarding the use of disinfectant
- Addition of warning regarding the use of DMSO
- Addition of instructions for use regarding the sealing procedure on the product bags and their handling before filling and freezing.
- Addition of instructions for use and symbol regarding storage in vapor phase of liquid nitrogen, thawing after storage in vapor phase of liquid nitrogen, and fluid transfer after thawing.
- Addition of an additional sentence within the warning section of the GMP variant of the CliniMACS Prodigy TS 521: “For the storage of cell fractions in the Product Bags, it is the responsibility of the user to define and verify the appropriate storage conditions.”

**Justification/Evaluation:** Content changes of labeling material, installation Aid, and package insert only.
The additional information for the users within the warning, precaution, and instruction for use section in the Package Insert prevent unforeseeable product misuse.

In this regard, no impact on the performance, quality, and safety of the affected products could be identified.

**Estimated Implementation** Q4/2021
Adaption of labelling material of CliniMACS Prodigy® TS 521

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