Introducing Generic Product and Carton Label to CliniMACS Tubing Sets (CE), addition of further translations and new precaution for package insert.

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS Tubing Set</td>
<td>200-073-104</td>
</tr>
<tr>
<td>CliniMACS Tubing Set LS</td>
<td>200-073-204</td>
</tr>
<tr>
<td>CliniMACS Depletion Tubing Set</td>
<td>200-073-404</td>
</tr>
</tbody>
</table>

**Category of change:** Update of documentation

**Current State:** CliniMACS Tubing Sets (CE) have individual product and carton labels containing static product data. The labels material are printing white adhesive paper sheets of DIN-A4 format with a permanent adhesive. Variable data are edited manually.

Further, the package insert of the CliniMACS Tubing Sets contains in total 21 languages: EN, CS, DA, DE, EL, ES, FI, FR, HR, HU, IT, NL, NO, PL, PT, RO, RU, SK, SL, SV, TR

**Planned change:** The raw material of the label will be changed. The new raw material for the label is a matt, woodfree, supercalendered paper with a permanent, waterborne acrylic adhesive and is delivered on rolls. These variable data are stored in the ERP system and will be imprinted during production directly from the ERP system.

Furthermore, the package insert of the **CE-marked CliniMACS Tubing Sets** will be adapted as follows:
- Addition of precaution regarding the use of disinfectants: „Any use of disinfectants on the product is exclusively within the responsibility of the user and risks must be assessed within the user’s own risk management."
- Addition of further translations AR, HE, SR, ET, BG, LT, LV languages in total)
- Harmonization of wordings.
Introducing Generic Product and Carton Label to CliniMACS Tubing Sets (CE), addition of further translations and new precaution for package insert.

Justification/Evaluation: The change of the printing procedure of the variable data will improve the manufacturing process and increase compliance of the labelling material. The additional information for the users within the warning, precaution, and instruction for use section in the Package Insert prevent unforeseeable product misuse.

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

Estimated Implementation: Q4/2022

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

27. Jun. 2022 i.V.

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