Introducing Generic Product and Carton Label to CliniMACS Prodigy Tubing Sets (CE) and CliniMACS Supplementary Bag (CE), addition of new translations and new precaution for package inserts

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
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<tbody>
<tr>
<td>CliniMACS Prodigy TS 500</td>
<td>200-073-601</td>
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<td>CliniMACS Prodigy TS 310</td>
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<td>CliniMACS Prodigy TS 510</td>
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<td>200-073-614</td>
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<tr>
<td>CliniMACS Supplementary Bag</td>
<td>200-076-612</td>
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</tbody>
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**Category of change:** Update of documentation

**Current State:** CliniMACS Prodigy Tubing Sets (CE) and CliniMACS Supplementary Bag (CE) have an individual product label. Also for the CE marked CliniMACS Prodigy Tubing Sets an individual carton label is available. 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

There is no precaution information regarding the use of disinfectants.

**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 Prodigy 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
- Harmonization of wordings.
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Furthermore, the package insert of the **CE-marked Supplementary Bag** 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
- Harmonization of wordings.
- Correction of spelling mistakes, US phone number
- Warning changed from: “Do not use if package is damaged. Risk of contamination. If the packaging is damaged, there is the risk of contamination. Before opening, inspect the packaging for damage, puncture or tears. Use the Supplementary Bag only if package is undamaged and sealed” to “Do not use if package is damaged. A damaged package could increase the risk of contamination. Before opening, inspect the packaging for damage, puncture or tears. Use the Supplementary Bag only if package is undamaged.”

**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**

Q1/2023

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