# Change Notification

**CC-21-0495**

## Revision of user manual for CliniMACS® Formulation Unit and CliniMACS® Electroporator

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
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<tbody>
<tr>
<td>CliniMACS® Formulation Unit</td>
<td>170-075-703</td>
</tr>
<tr>
<td>CliniMACS® Electroporator</td>
<td>170-075-704</td>
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### Category of change:
- User Manual

### Current State:
- CliniMACS® Formulation Unit is delivered with the English User Manual 200-038-031-ver01.
- CliniMACS® Electroporator is delivered with the English User Manual 200-038-030-ver02 and ver03 is implemented and ordered.

### Planned change:
- CliniMACS® Electroporator User Manual and CliniMACS® Formulation Unit User Manuals:
  - Revision of both manuals to be in compliance with the valid regulatory demands for risk and warning information and to follow the valid Miltenyi Biotec layout for Instrument User Manuals.

  Additionally for the CliniMACS® Formulation Unit:

  CliniMACS® Formulation User Manual:
  - Adapations from Change Notification CC-21-0034 for the technical support information will be included
  - Following Change Notification CC-20-0077 the US disclaimer on the front page of the CliniMACS® Formulation User Manuals needs to be changed from “Investigational System” to “Clinical Research System”
  - Declaration of Conformity for the United Kingdom including the corresponding Standards has to be included. The necessary RER is described in an additional change which deals with all labelling changes in the course of the Brexit. This change is currently under preparation. Inclusion of UK DoC in bill of material of CliniMACS Formulation Unit.

  CliniMACS® Formulation Unit product and carton label:
  - Inclusion of symbols of Conformity for the United Kingdom and adaption of headline

### 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.
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| Estimated Implementation | Q2/2022 |

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.Jan.2022
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG