Canada specific products for CliniMACS® System Components

<table>
<thead>
<tr>
<th>Product</th>
<th>New REF</th>
<th>Regulatory Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS CD34 Reagent</td>
<td>200-070-265</td>
<td>CAN</td>
</tr>
<tr>
<td>CliniMACS Anti-Biotin Reagent</td>
<td>200-070-266</td>
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<tr>
<td>CliniMACS TCRα/β-Biotin</td>
<td>200-070-267</td>
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<tr>
<td>CliniMACS CD19 Reagent</td>
<td>200-070-268</td>
<td>CAN</td>
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<tr>
<td>CliniMACS Cytokine Capture System (IFN-gamma)</td>
<td>200-070-269</td>
<td>CAN</td>
</tr>
</tbody>
</table>

**Category of change:** Change of regulatory requirements and status

**Current State:** Different regulatory variants of the above mentioned CliniMACS Reagents are used in Canada

**Planned change:** New Canadian specific product variants will be introduced for above mentioned CliniMACS Reagents.

The compliance statement on the product quality certificates of all products in scope will be adapted as follows:

The above mentioned medical device was licensed by Health Canada according to Section 36 of Canadian Medical Devices Regulations SOR/98-282. We ensure and declare that we fulfill the obligations imposed by Part 1 of Canadian Medical Devices Regulations SOR/98-282, and that the above mentioned medical device meets the Safety and Effectiveness Requirements of Canadian Medical Devices Regulations articles 10 – 20. The establishment and maintenance of a quality system according to ISO 13485 under MDSAP was certified by the certification body TÜV SÜD America Inc.

The following regulatory and legal notes in the package insert of CliniMACS CD34 Reagent and CliniMACS Cytokine Capture System (IFN-gamma) will be added:

In Canada, any clinical application of the output product must be performed in accordance with applicable Canadian legislation and regulations that pertain to cellular therapies (e.g. for advanced cellular therapies, the applicable sections of the Food and Drugs Act and the Food and Drug Regulations).

Note: This disclaimer was already present in the CliniMACS TCRα/β-Biotin, CliniMACS Anti-Biotin Reagent and CliniMACS CD19 Reagent Package Insert CE and therefore remains the same in the new Canadian version.
Change Notification
CC-21-0067

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Justification/Evaluation: Above mentioned regulatory status adaption are required due to labeling requirements for the Canadian market. As these requirements cannot be combined with other regulatory status such as CE labeling for the European market, new product numbers have to be introduced. Beside the packaging inserts and user manuals the products remain the same and are identical with equivalent products with other regulatory status.

The new Canadian specific label versions will be incorporated within the Medical Device Licenses No: 64566 and 99376 respectively.

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 Q4/2021

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

15.Jul.2021

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