Adaption of Product Quality Certificates and Certificates of Analysis of CliniMACS® CD34 products

<table>
<thead>
<tr>
<th>Product</th>
<th>Regulatory Status</th>
<th>Material No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CliniMACS® CD34 Reagent</td>
<td>CE</td>
<td>200-070-100</td>
</tr>
<tr>
<td>CliniMACS® CD34 Reagent</td>
<td>Australia</td>
<td>200-070-270</td>
</tr>
<tr>
<td>CliniMACS® CD34 GMP MicroBeads</td>
<td>MACS GMP</td>
<td>170-076-711</td>
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Category of change: Change of Product Quality Certificates and Certificates of Analysis

Current State: A Product Quality Certificate (PCQ) or a Certificate of Analysis (CoA) is issued for each product lot of above mentioned CliniMACS CD34 products.

The PQC/CoA of CliniMACS CD34 Reagent and CliniMACS CD34 GMP MicroBeads indicate Endotoxin and Sterility testing only.

Planned change: The Certificates of Analysis and Product Quality Certificates will be revised.

Following tests will be added to the CliniMACS CD34 Reagent and CliniMACS CD34 GMP MicroBeads certificates: OD450, Free Dextran and biological performance (CD34 Selection Assay).

All remaining Certificates of Analysis will be replaced by the Product Quality Certificate by this change.

Justification/Evaluation: There is an update on regulatory statement only. All tests, which will be stated in the PQC in future, are performed already. Statement of the test results will increase customer satisfaction.

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: Q2/2021

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

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