Update of data sheet of MACS® GMP Recombinant Human IL-7 and MACS GMP Recombinant Human IL-15

<table>
<thead>
<tr>
<th>Product</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACS GMP Recombinant Human IL-7</td>
<td>170-076-111</td>
</tr>
<tr>
<td>MACS GMP Recombinant Human IL-15</td>
<td>170-076-114</td>
</tr>
</tbody>
</table>

**Category of change:** Update of data sheet.

**Current State:** A data sheet is available for above mentioned MACS GMP Recombinant Human IL-7 (25 µg) and MACS GMP Recombinant Human IL-15 (25 µg) on the website of Miltenyi Biotec. The data sheets are specific for the mentioned product sizes (25 µg) and state different specifications (e.g. purity, host cell DNA, host cell protein etc.). There is no information listed regarding the source of the product.

**Planned change:** MACS GMP Recombinant Human IL-7 size 100 µg (REF 170-076-184) will be added to the data sheet of the respective 25µg sized product. Individual specifications will be replaced by “For detailed specifications of MACS GMP Recombinant Human IL-7 please refer to the respective Product Quality Certificate (PQC)”. MACS GMP Recombinant Human IL-15 size 100 µg (REF 170-076-186); will be added to the data sheet of the respective 25µg sized product. Information on source of the product (E.coli) will be added and wording will be changed from “Certificate of Analysis (CoA)” to “Product Quality Certificate (PQC)” in accordance to Change Notification CN_CC-20-0233.

**Justification/Evaluation:** The data sheets are formally updated by addition of new filling sizes. The deletion of individual specifications from data sheet of MACS GMP Recombinant Human IL-7 bears no risk as the specifications themselves are not changed and are still provided via the Product Quality Certificate. The addition of information of the source (E.coli) to the data sheet of MACS GMP Recombinant IL-15 leads to a harmonization of data sheets for MACS GMP cytokines only.

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

**Estimated Implementation** Q4/2021
Change Notification
CC-21-0234

Update of data sheet of MACS® GMP Recombinant Human IL-7 and MACS GMP Recombinant Human IL-15

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

25.Oct.2021
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG