Change Notification
CC-21-0387

Prolongation of shelf life of MACS® GMP PBS/MgCl₂ Buffer and MACS GMP Tytonase

Product | REF
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MACS® GMP PBS/MgCl₂ Buffer | 170-076-155
MACS® GMP Tytonase | 170-076-210

Category of change: Adaption of Shelf life

Current State: The MACS® GMP PBS/MgCl₂ Buffer has a shelf life of 35 months after sterilization when stored at room temperature. The MACS® GMP Tytonase has a shelf life of 3 months when stored at 2 - 8°C.

Planned change: The shelf life of MACS® GMP PBS/MgCl₂ Buffer will be extended to 59 months after sterilization when stored at room temperature. The shelf life of MACS® GMP Tytonase will be extended to 6 months when stored at 2 - 8°C. Prolonged shelf life will be indicated on the label.

Justification/Evaluation: Based upon actual data provided by ongoing real time stability studies which support a prolonged shelf life, the shelf life of the MACS® GMP PBS/MgCl₂ Buffer and MACS® GMP Tytonase can be adapted accordingly.

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

Estimated Implementation: Q1/2022

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

07.Jan.2022

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