Change Notification
CC-22-0129

Prolongation of shelf life for Lentiviral Vector (anti-) CD19 CAR

Product REF
Lentiviral Vector (anti-) CD19 CAR 200-072-100

Category of change: Prolongation of shelf life

Current State:
According to real time data generated within a stability study a shelf life of 36 months at -70°C after production is declared for the Lentiviral Vector (anti-) CD19 CAR.

Planned change:
Based on real time stability data as part of a new stability study the shelf life for the Lentiviral Vector (anti-) CD19 CAR will be prolonged to 48 months at -70°C after production.

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.

Estimated Implementation
May 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.

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