Change Notification
CC-21-0048

Update of CliniMACS Prodigy® App-Software Adherent Cell Culture of CliniMACS Prodigy Instrument

Product: CliniMACS Prodigy Instrument
Material No.: 200-075-301

Category of change: Software Update

Current State: The CliniMACS Prodigy Instrument, Prodigy App-SW Adherent Cell Culture version 1.0.3 is in use.

Planned change: The Prodigy App-SW Adherent Cell Culture will be updated to version 1.1.

This update includes:
- Usability improvement:
  - New CliniMACS Prodigy TS 730 (200-073-623) can be used.
  - "Undo" button is activated on final check screen to lead back to main menu.
- GUI changes: "1 m Tube Extension" is replaced by "CliniMACS Accessories".
- Bugfixes: Skipping is not allowed anymore once the integrity test is executed.
- Volume reduction during harvest: During the harvest module, volume reduction to 30mL was achieved by using the parabola method. An additional volume reduction is now added by an additional removal of liquid via the upper port in the chamber
- UDI code implementation

Justification/Evaluation: The planned software Update is assessed as very low risk and serves mainly as bugfix and improvement.

Due to the volume reduction, a longer centrifugation time is necessary, which was assessed as not critical. There is also no increased risk of losing cells during the harvest module, as the additional volume reduction is performed via the upper port after the Parabola method. This leads to an accumulation of the cells at the lower part of the chamber wall.
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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 Q3/2021

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

18. May. 2021
Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG