CliniMACS® Tubing Set raw material supplier change

### Category of change:
Change of raw material

### Current State:
Cell Bag is one of the raw materials used in the manufacturing of the above-mentioned CliniMACS Tubing Sets. This Cell Bag is supplied by a qualified supplier of Miltenyi Biotec.

### Planned change:
The current supplier will be replaced by another qualified supplier. The dimensions and materials of the Cell Bag will remain the same. Replacement supplier produces the Cell Bag, in the same way, using the same materials used by the current supplier.

### Justification/Evaluation:
As the production and distribution of Cell Bag was discontinued by the current supplier, replacement supplier was sourced and identified.

Replacement supplier is certified according to ISO 13485:2016 and registered as a qualified supplier of Miltenyi Biotec. Regular audits have been performed.

Risks concerning functionality, integrity, sterility, biocompatibility, endotoxins, and particles of the CliniMACS Tubing Sets have been considered for evaluation. Incoming goods inspection procedure, release criteria, and tests of the CliniMACS Tubing Sets remain the same.

Overall no new or increased risk to the products’ safety, reliability, or performance are to be expected.

### Estimated Implementation
Q1/2022
Change Notification
CC-21-0195

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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