Adaption of labeling materials of CliniMACS® Electroporator

Product
CliniMACS Electroporator

Material No.
170-075-704

Category of change:
Adaption of labelling

Current State:
Labelling materials and a manual are available for the CliniMACS Electroporator.

Planned change:
The Manual of the CliniMACS Electroporator will be updated as follows:
- Addition of EAC und UKCA symbol and corresponding standards
- Adaption of section of serious incidents
- Addition of regulatory information for the US
- Translations of Instrument Manual

The EAC and UKCA symbol will be added to the label, as well as a new phone number.

Justification/Evaluation:
Additional information is placed on manual and label according to regulatory requirements.

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
Q4/2021

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

01.Jul.2021

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