Change Notification
CC-21-0147

Change of labelling of MACS® GMP Tyto® Cartridge

Product: MACS® GMP Tyto® Cartridge
REF: 170-076-011

Category of change: Label change

Current State: A label is placed on product, blister and carton of above mentioned MACSQuant Tyto Cartridges.

Planned change: The label of the MACSQuant Tyto Cartridges will be updated and include the following changes:
- Addition of CE mark for RoHS conformity and mark for applicability of WEEE directive
- Change of company name to Miltenyi Biotec B.V. & Co. KG
- Change of company logo

Justification/Evaluation: Addition of CE mark for RoHS conformity and WEEE mark are required due to regulatory requirements. Due to reorganization from Miltenyi Biotec GmbH to Miltenyi Biotec B.V. & Co.KG (please see Change Notification CN_CC-19-0305) the new name will be mentioned on the labels. Due to logo change (please see Change Notification CN_CC-20-0041) the new logo will be shown on the revised labels.

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

Estimated Implementation: Q3/2022

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

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