## Change of carton labelling of CliniMACS® Reagents

### Product | REF No.
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CliniMACS CD34 Reagent | 200-070-100 (171-01)
CliniMACS CD3 Reagent | 200-070-113 (273-01)
CliniMACS CD1c (BDCA-1)-Biotin | 200-070-114 (277-01)
CliniMACS CD8 Reagent | 200-070-115 (275-01)
CliniMACS CD19 Reagent | 200-070-117 (179-01)
CliniMACS CD14 Reagent | 200-070-118 (272-01)
CliniMACS Anti-Biotin Reagent | 200-070-120 (173-01)
CliniMACS CD45RA Reagent | 200-070-146 (701-46)
CliniMACS CD45RA Reagent XS | 200-070-126 (-/-)
CliniMACS CD56 Reagent | 200-070-128 (271-01)
CliniMACS CD25 Reagent | 200-070-131 (274-01)
CliniMACS CD4 Reagent | 200-070-132 (276-01)
CliniMACS CD304 (BDCA-4) Reagent | 200-070-133 (278-01)
CliniMACS TCRα/β-Biotin | 200-070-148 (-/-)
CliniMACS Cytokine Capture System (IFN-gamma) | 200-070-111 (279-01)

### Category of change:
Change of carton labelling

### Current State:
A label is present on the carton label of above mentioned CliniMACS Reagents.
An UDI sign is presented already, but no UDI Code.
A separate label with barcode and the REF number of the product is added to the carton box.

### Planned change:
The UDI barcode will be added to the carton label under the UDI sign.
The REF number will be integrated in the UDI barcode and the separate label with barcode will be deleted.

### Justification/Evaluation:
There is a change of carton label only. All required information is still presented on the label.

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
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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.

p.p. 16 Jun 2021

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