Change Notification
CC-21-0502

Change of statements on Product Quality Certificates for products regulated by MDR

Product
CliniMACS® Reagents and Biotin Conjugates
CliniMACS® PBS/EDTA Buffer
CliniMACS® and CliniMACS® Prodigy Tubing Sets
CryoMACS® Freezing Bags
TheraSorb®
MACS® ART
CliniMACS® Instruments

Category of change: Labelling

Current State: 1) Current Product Quality Statement for CliniMACS® Reagents and Biotin Conjugates for “CE (MDR)” contains following parts:

“The above mentioned medical device was certified by the notified body TÜV SÚD Product Service GmbH
Ridlerstrasse 65
80339 Munich
Germany
according to Annex IX, MDR (EU) 2017/745.
[...] The establishment and maintenance of a quality system according to ISO 13485 was certified by the TÜV SÚD Product Service GmbH. Application of the full quality assurance system approved for the design, manufacture and final inspection of the above mentioned product, was certified according to Annex IX, Chapter I, MDR (EU) 2017/745 by the TÜV SÚD Product Service GmbH (0123).”

2) Current Product Quality Statements for CliniMACS® Prodigy, CliniMACS® Plus Instrument, CryoMACS® Freezing Bags, CliniMACS® PBS/EDTA Buffer, CliniMACS® Tubing Sets, CliniMACS® Prodigy Tubing Sets, MACS® ART products and TheraSorb® products for “CE (MDR)” contain following part:

“The establishment and maintenance of a quality system according to ISO 13485 was certified by the TÜV SÚD Product Service GmbH (0123). Application of the full quality assurance system approved for the design, manufacture and final inspection of the above mentioned product was certified by the notified body TÜV SÚD Product Service GmbH
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Monthly 69
80339 Munich
Germany
according to Annex IX, Chapter I, MDR (EU) 2017/745.”

Planned change:

1) Applied chapters (Chapter II and Chapter III, respectively) of Annex IX, MDR regarding conformity assessment are added to Product Quality Statement for CliniMACS® Reagents and Biotin Conjugates for “CE (MDR)”:

“The above mentioned medical device was certified by the notified body TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Munich
Germany
according to Annex IX, Chapter II, MDR (EU) 2017/745.
[…]
The establishment and maintenance of a quality system according to ISO 13485 was certified by the TÜV SÜD Product Service GmbH. Application of the full quality assurance system approved for the design, manufacture and final inspection of the above mentioned product, was certified according to Annex IX, Chapter I and III, MDR (EU) 2017/745 by the TÜV SÜD Product Service GmbH (0123).”

2) Applied chapter (Chapter III) of Annex IX, MDR regarding conformity assessment is added to part of Product Quality Statement for CliniMACS® Prodigy, CliniMACS® Plus Instrument, CryoMACS® Freezing Bags, CliniMACS® PBS/EDTA Buffer, CliniMACS® Tubing Sets, CliniMACS® Prodigy Tubing Sets, MACS® ART products and TheraSorb® products for “CE (MDR)”:

“The establishment and maintenance of a quality system according to ISO 13485 was certified by the TÜV SÜD Product Service GmbH (0123). Application of the full quality assurance system approved for the design, manufacture and final inspection of the above mentioned product was certified by the notified body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
according to Annex IX, Chapter I and III, MDR (EU) 2017/745.”
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The regulatory requirements for Medical Devices Directive 93/42/EC products will be still covered and the product quality statements untouched by this change.

**Justification/Evaluation:** Affected Product Quality Certificate Statements are adapted for clarification only. 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**
- Q2/2022: CliniMACS® Reagents and Biotin Conjugates
- Q4/2022: CliniMACS® PBS/EDTA Buffer
- Q4/2022: CliniMACS® and CliniMACS® Prodigy Tubing Sets
- Q4/2022: CryoMACS® Freezing Bags
- Q1/2022 and Q3/2022: TheraSorb®
- Q1/2022 and Q4/2022: MACS® ART
- Q1/2022: CliniMACS® Instruments

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

21.Feb.2022

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