
Product | REF
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CliniMACS Prodigy EP-2 GMP | 170-076-623
CliniMACS Prodigy EP-2 CR | 200-073-624
CliniMACS Prodigy EP-4 GMP | 170-076-624
CliniMACS Prodigy EP-4 CR | 200-073-625

Category of change: Change of packaging

Current State: CliniMACS Prodigy EP-2 and CliniMACS Prodigy EP-4 are packed without any support for the electrodes of the electroporation cuvette.

Figure 1 Electroporation Cuvette in tray; electrodes with direct contact to foil of primary packaging

Planned change: A cuvette protector will be introduced as additional packaging component within the sterile barrier. It will be placed onto the electrodes of the Electroporation Cuvette as shown below.

Figure 2 Electroporation Cuvette with transparent cuvette protector (tray shown without primary packaging)

**Justification/Evaluation:**

The additional packaging component will better protect the electroporation cuvette in the packaging against exterior influences and damages. Additionally it ensures that the product and sterile barrier keeps functional. The cuvette protector is a flat small light weight component made of PETG thermoformed foil which does not significantly increase the total weight of the product.

The PETG thermoformed foil is known from other packaging materials used within the CliniMACS Prodigy Tubing Set product group and does not have adherent properties for microorganisms. Therefore, the effect on the recovery of the microorganisms in the bioburden determination is negligible. The stability and irradiation (gamma) resistance of the foil material is validated already.

The cuvette protector has no fluid contact and therefore does not affect the biocompatibility of the product itself.

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

Manager QA Audit/Customer/Supplier
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