



Miltenyl Biotec

Certificate of Analysis

Product: CryoMACS® Freezing Bag 250
 REF-No.: 200-074-401
 Part-No.: 74401
 Lot No.: 6181015004
 Use-by Date: 2021-09-15

Sterilization Method: E-beam according to ISO EN 11137

Sterilization Date: 26.Nov.2018

Required Testing	Specification*	Results
Sterility	sterile	conforms
Endotoxin	NMT 0.5 EU/ml	conforms

*NMT = Not more than

CryoMACS® Freezing Bags are manufactured and controlled under an ISO 13485 certified quality system. In Europe, the CryoMACS® Freezing Bags are available as CE-marked medical devices. In the U.S.A. the CryoMACS® Freezing Bags are 510k cleared.

We ensure and declare that we fulfill the obligations imposed by Annex II, excluding section 4, MDD 93/42/EEC, and that the above mentioned medical device meets the Essential Requirements of Annex I, MDD 93/42/EEC.

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 II, excluding section 4, MDD 93/42/EEC.

17 DEC 2018

Quality Assurance
Eik Pauluhn

Date

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