Certificate

mdc medical device certification GmbH

certifies that

Biomex GmbH Siemensstraße 38 69123 Heidelberg Germany

with the locations listed in the attachment

for the scope

production of blood and blood plasma products and other human specimens (e.g. PBMC isolation from leukocyte donations);
distribution of biological, chemical and biochemical materials;
services related to performance evaluation studies for
IVD manufacturers;

performing of prospective / retrospective studies as well as functional tests with stimulated PBMCs

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2015)

 Valid from Valid until
 2023-09-22

 Valid until
 2026-06-21

 Registration no.
 D1293700018

 Report no.
 P23-00621-273809

 Stuttgart
 2023-08-15

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1293700018

date 2023-08-15

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Location	Scope
Biomex GmbH Hans-Bunte-Straße 6 69123 Heidelberg	production of blood and blood plasma products and other human specimens (e.g. PBMC isolation from leukocyte donations);
	distribution of biological, chemical and biochemical materials;
	services related to performance evaluation studies for IVD manufacturers;
	performing of prospective / retrospective studies as well as functional tests with stimulated PBMCs
Biomex GmbH Siemensstraße 38 69123 Heidelberg	production of blood and blood plasma products and other human specimens (e.g. PBMC isolation from leukocyte donations);
	distribution of biological, chemical and biochemical materials;
	services related to performance evaluation studies for IVD manufacturers;
	performing of prospective / retrospective studies as well as functional tests with stimulated PBMCs
Plasmazentrum Heidelberg Hans-Böckler-Straße 2a 69115 Heidelberg	production of blood and blood plasma products and other human specimens (e.g. PBMC isolation from leukocyte donations); services related to performance evaluation studies for IVD manufacturers;
Plasmazentrum München Dachauerstraße 4 80335 München	production of blood and blood plasma products and other human specimens (e.g. PBMC isolation from leukocyte donations);



Head of Certification Body