EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

CE-Immundiagnostika GmbH Karl-Landsteiner-Str. 6 69151 Neckargemuend Germany

for the scope

Reagents for blood typing: AB0 system, Rhesus (C, c, D, E, e), Kell system, Duffy system, Kidd system and determination of anti-irregular erythrocytes

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/FC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from 2019-07-22 Valid until 2021-06-30 Registration no. D1415300012 Report no. P19-00685-147028 Stuttgart 2019-07-22

Head of Certification Body





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