## **EC** Certificate

#### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that



# Gesellschaft für Biochemica und Diagnostica mbH Max-Planck-Ring 21 65205 Wiesbaden Germany

for the scope

testkits for the determination of HIV, HBV, HCV, tumour marker PSA, Rubella, Toxoplasmosis, Chlamydia and CMV, blood group test sera: ABO system, rhesus system (D)

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 – Section 3 of the Council Directive 98/79/EC

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.

This certificate is valid until: 2014-03-11 Certificate registration no.: 0063.21.21/0

Report no.: E 0063.21 / 2009-03-11

Stuttgart 2009-03-11

Head of Certification Body



