EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

bioactiva diagnostica GmbH
Louisenstraße 137
61348 Bad Homburg
Germany

for the scope

ELISA-testkits for the determination of Toxoplasma, Rubella, CMV, Chlamydia

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/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.

Valid from	2022-04-11
Valid until	2025-05-26
Registration no.	D1155300014
Report no.	P21-01579-234772
Stuttgart	2022-04-11

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de