EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith grants

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

for the scope

anti-HIV 1/2 ELISA for the detection of antibodies to human immunodeficiency virus types 1 and 2 (HIV-1, HIV-2) in human serum and plasma

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex IV – Section 4 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.

This certificate is only valid in connection with a valid mdc certificate according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from Valid until Registration no.

Report no. Stuttgart 2018-01-26

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Head of Certification Body





Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de