

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**DiaMex GmbH
Siemensstraße 38
69123 Heidelberg
Germany**

for the scope

**controls for
HIV 1 and 2, HTLV I and II, Hepatitis B and Hepatitis C (List A);
controls for
Rubella, Toxoplasmosis, Cytomegalovirus, Chlamydia and PSA (List B)**

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	2014-09-08
Valid until	2019-09-08
Registration no.	D1329000007
Report no.	P14-01434-28751
Stuttgart	2014-09-08



Head of Certification Body



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