

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Mikrogen GmbH  
Floriansbogen 2 - 4  
82061 Neuried  
Germany**

for the scope

**Westernblots, Line assays and ELISAs for the detection of antibodies against  
CMV (Cytomegalovirus), Chlamydia, Rubella virus, Toxoplasma gondii,  
HCV (Hepatitis C virus) and HIV-1 & HIV-2 (Human immunodeficiency virus),  
Control sera for CMV (Cytomegalovirus), Chlamydia, Rubella virus, Toxoplasma gondii**

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	2011-07-12
Valid until	2012-07-06
Registration no.	0200.21.11/1
Report no.	E 0200.21 / 2011-07-12
Stuttgart	2011-07-12



Head of Certification Body

