



Product Service

EC - CERTIFICATE

Full Quality Assurance System

(Annex IV, section 3 of the Directive 98/79/EC on
In Vitro Diagnostic Medical Devices)

No. V1 09 02 50560 005

Manufacturer:	Viro-Immun Labor-Diagnostika GmbH In der Au 29 61440 Oberursel GERMANY
Facility(ies):	Viro-Immun Labor-Diagnostika GmbH In der Au 29, 61440 Oberursel, GERMANY
Product Category(ies):	Products for determination of infection markers Chlamydia, Rubella, Toxoplasma, Cytomegalovirus
Model(s):	ELISA and IFA for the determination of antibodies against Chlamydia, Rubella, Toxoplasma and Cytomegalovirus

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product families according to Annex IV section 3 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. This quality assurance system conforms to the relevant provisions of this Directive and is subject to periodical surveillance. For marketing of Annex II list A products an additional Annex IV.4 certificate is mandatory. See also notes overleaf.

Report no.: 71344322

Valid until: 2014-02-10



Hans-Heiner Junker

Date, 2009-02-11

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices with identification no. 0123.

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