

# EC-Declaration of conformity for In-vitro-diagnostics

(according to annex III of directive 98/79/EC for in-vitro-diagnostics)

The procedure for EC declaration established according to annex IV – full quality assurance system in accordance to DIN EN ISO 13485:2003 for producers of medical devices.



We,

**Name of producer:** MedInnovation GmbH

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herewith confirm, that the following laboratory devices are manufactured in compliance with the rules and regulations of the European Directive 98/79 and its valid norms:

**Name of product:** ESR-Analyzer for in-vitro-diagnostic test MMS

**Type:** MMS-In-Vitro-Diagnostic-Test

**Serial-numbers:** 01-08-xxx ff.

For verification of the product in view of electro-magnetical capability and technical security, the following harmonized European norms have been considered, which are published in the official register of the European Community:

Low Voltage Guideline no. 72/23EWG dd. 19.02.1973, incl. alteration-guideline no. 93/68/EWG;

EMC-Guideline no. 89/336/EWG dd. 03.05.1989 incl. alteration-guideline no.92/31/EWG according to norms for laboratory devices no. IEC EN 61326-1 and IEC EN 61000 ff.

Observance of the electro-magnetical capability ( EMC ) has officially been confirmed by audit-report no. 21119087-001 dd. 27.4.2005 issued by TÜV Rheinland Product Safety GmbH, Berlin.

Safety requirements for electrical equipment for measurement, control and laboratory use have been confirmed by the audit report no. 21119198-001 dated 03.06.2005, issued by TÜV Rheinland Product and Safety GmbH, Berlin according to IEC EN 61010-1.

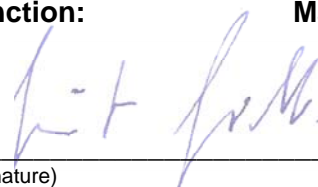
Particular requirements for in vitro diagnostic (IVD) medical equipment have been confirmed by the audit report no. 21119198-002 dated 03.06.2005, issued by TÜV Rheinland Product and Safety GmbH, Berlin according to IEC EN 61010-2-101.

**This declaration of conformity is given for all identical specimen of devices, which are produced in accordance with respective documents of the technical documentation, which is basical component of this declaration.**

Berlin,  
June 15<sup>th</sup>, 2005

**Name of underwriter:** Cert. Eng. Econ. Günter Seibt

**Function:** Managing Director

  
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(Signature)