



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 08 09 49408 022

**Manufacturer:** BAG Health Care GmbH

Amtsgerichtsstr. 1-5  
35423 Lich  
GERMANY

**Facility(ies):**

BAG Health Care GmbH  
Gottlieb-Daimler-Str. 24, 35423 Lich, GERMANY

BAG Health Care GmbH  
Amtsgerichtsstr. 1-5, 35423 Lich, GERMANY

**Product  
Category(ies):**

**Products according to Directive 98/79/EC  
Annex II**

**Model(s):** see Attachment

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.:** 71338731

**Valid until:** 2013-09-29



Hans-Heiner Junker

**Date,** 2008-09-30

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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dated 2008-09-30**

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**Products according to annex II list A:**

Testsera for determining the following blood groups: ABO, Rhesus D, Rh-subgroups and Kell as specified in the corresponding Design Examination certificates

**Products according to annex II list B:**

Reagents for determining HLA-tissue types A, B, DR:

- HISTO TRAY
- HLA-Sera
- Rabbit-Complement
- HISTO TYPE DNA

Testsera for determining the following blood groups: anti-Duffy and anti-Kidd:

- Anti-Fy (Duffy) polyclonal
- Anti-Fy (Duffy) polyclonal
- Anti-Jk (Kidd) polyclonal
- Anti-Jk (Kidd) polyclonal
- Anti-Jk (Kidd) monoclonal (IgM)
- Anti-Jk (Kidd) monoclonal (IgM)

Reagents for determining irregular anti-erythrocytic antibodies:

- Anti-Human-Globulin GREEN (IgG + C3d) monoclonal
- Anti-Human-Globulin-Serum GREEN (Anti-IgG + Anti-C3) rabbit

Reagents for determining of markers of Chlamydia Infection :

- Enzyme immunoassays for the determination of antibodies against Chlamydia
- Multiplex PCR-ELISA System for the detection of Chlamydia

Enzyme immunoassays for detection of IgA/IgG/IgM antibodies against *Toxoplasma gondii*:

- BAG-Toxo-EIA-A
- BAG-Toxo-EIA-G
- BAG-Toxo-EIA-M

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Enzyme immunoassays for detection of IgA/IgG/IgM antibodies against Rubella virus:

- BAG-Rubella -EIA-G
- BAG-Rubella -EIA-M

Enzyme immunoassays for detection of IgA/IgG/IgM antibodies against Cytomegalovirus:

- BAG-CMV-EIA-A
- BAG-CMV-EIA-G
- BAG-CMV-EIA-M

Munich, CRT-2, 2008-09-30

Hans-Heiner Junker

