



## **Medion Grifols Diagnostics AG Quality System**

Medion Grifols Diagnostics AG, a manufacturer of medical devices for In-vitro Diagnostics, maintains a Quality System which meets the requirements of the following regulations or standards.

### **Quality system regulations, 21 CFR Part 820**

**IVD-Directive 98/79/EC**

**EN ISO 13485: 2003 / AC: 2009**

**EN ISO 9001: 2008**

**CMDCAS**

Medion Grifols Diagnostics AG certifies that the products are manufactured in accordance with the European IVD-Directive 98/79/EC and/or United States Good Manufacturing Practice regulations.

The required Quality System is established since 1991 throughout the company and contains information about SOP's and Policies and processes.

Medion Grifols Diagnostics AG is regularly inspected by FDA (CBER and CDRH) and the Notified Body TÜV SÜD Product Service GmbH.

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