Dr. T. Matthias
AESKU.DIAGNOSTICS
Mikroforum Ring 2
55234 Wendelsheim
Tel.: + 49-6734-9627-0
Fax.: + 49-6734-962727

Declaration of Conformity according to European Directive on in vitro diagnostic medical devices (98/79/EG) of the Medical Devices Act (MPG)

I declare that all in vitro diagnostics manufactured by

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Germany

have been manufactured according to the Annex III of the European Directive on in vitro diagnostic medical devices 98/79/EG of the Medical Devices Act (MPG) and that all these fulfil the requirements for in vitro diagnostica according to Annex I of the Directive 98/79/EG and therefore are allowed to be CE signed.
As all our products are none of Annex II of the European Directive, the CE mark needs not to be certified by a competent authority.

Notification of our products

The notifications of your CE-marked IVD products manufactured in Germany according to §25 Medical Device Act (MPG) was registrated under the code: **33/9001**
Competent authority: DE/CA33

The notifications of our CE-marked IVD products manufactured in Germany were registrated under the codes listed in Table 1.

Quality management

AESKU.DIAGNOSTICS has established a quality system for the design/development and production of in vitro diagnostica and life science products as well as their distribution, which was Our quality management according to DIN EN ISO 9001: 2000 was certified by the Institute for Certification and Testing Eurocat (Registration no. 0535) in 2001, in 2003 we gained certification according to DIN EN ISO 13485: 2003. It embraces all the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices.

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