

For presentation to the Authorities of Moldavia

Declaration

Dear Sir / Madam,

We, Roche Diagnostics GmbH, Mannheim, Federal Republic of Germany herewith confirm that the products which are placed on the market in the sense of Directive 98/79/EEC in the EEA and which bear the CE-mark comply with this mentioned directive. This statement is true for the following products:

- Clinical Chemistry (Hitachi instruments, Hitachi system reagents, Hitachi HIA reagents, Integra instruments, Integra system reagents, Integra HIA reagents, laboratory integration hardware, cobas 6000, cobas c 501 and 502 system, cobas c 501 and 502 system reagents)
- Immunodiagnostics (Cobas Core instruments and reagents, Elecsys instruments and reagents, cobas 6000, cobas 8000 cobas e 601 and 602 system, cobas e 601 and 602 system reagents)
- Urinalysis (Miditron, UriSys 1100 and cobas u411 instruments and strips)
- Bloodgas analysis (9180, cobas b 121, cobas b 221, cobas b 123 analyzer and system reagents)
- Near-Patient Testing (Primary Care, Hospital POC, Coagulation monitoring, consumer products, cobas 101 analyzer and reagents)

Mannheim, July 19, 2013

Roche Diagnostics GmbH
i.V. i.V.

Dr. Bayer

S. Grigarrczik

