

Declaration of Conformity



according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer:

Dirui Industrial Co., Ltd.

95 Yunhe Street New& High Tech. Development Zone

Changchun, Jilin 130012 P.R. China

Authorised

representative : Emergo Europe

Molenstraat 15 2513 BH The Hague

The Netherlands

Medical Device: product Name: Urinalysis Hybrid

IVDD-Classification: Professional use

Lot/batches/Serial

number, Type, Periods: FUS-2000

of manufacture (where applicable)

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.

May 31, 2013

Representalive:

Changchun, China

Ge Yu

Dirui Industrial co., Ltd.

(place and date of issue)

(name and signature or equivalent marking of authorized person)