CE Declaration of Conformity CE

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

Authorized representative : Emergo Europe

Molenstraat 15 2513 BH The Hague The Netherlands

Medical Device : Product Name: Reagent for Urine Sediment Analyzer

IVDD-Classification: Professional Use

Lot/batches/Serial number, Type, Periods of manufacture (where applicable)

Urine Sediment Analyzer Reagent-Sheath
Urine Sediment Analyzer Reagent-Diluent
Urine Sediment Analyzer Reagent-Standard Solution
Urine Sediment Analyzer Reagent-Detergent
Urine Sediment Analyzer Reagent-Focus
Urine Sediment Analyzer Reagent-Positive Control
Urine Sediment Analyzer Reagent-Negative Control

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 Directive98/79/EC, Annex III.

Valid Since

May 15th, 2012

Representative:

Changchun, China

Dirui Industrial Co., Ltd.

DIRUI INDUSTRIAL CO., LTD 长春迪瑞医疗科技股份有限公司

(place and date of issue)

(name and signature or equivalent marking of authorized person)