DIRUI 迪瑞

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**Dirui Industrial Co., Ltd.** **95 Yunhe Street New& High Tech. Development Zone** **Changchun , Jilin 130012 P.R. China**

We declare under our sole responsibility that

The medical device: /	**Product name :DIRUI H Series Urine Analyzer** **Model : DIRUI H-50 Urine Analyzer** **DIRUI H-100 Urine Analyzer** **DIRUI H-300 Urine Analyzer** **DIRUI H-500 Urine Analyzer** **DIRUI H-800 Urine Analyzer** **DIRUI H-800(PLUS) Urine Analyzer**
Intended purpose: /	**Professional use**
IVDD-Classification: /	**General/Other**

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.

Conformity assessment procedure: /	**Directive 98/79/EEC Annex I, excluding Section 4**
Authorised representative: /	**Emergo Europe** **Molenstraat 15 2513 BH The Hague** **The Netherlands**
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

2015

Representative:

Changchun,China

Place, date /

Dirui Industrial co. Ltd.

Name and function /