



EC DECLARATION OF CONFORMITY


PRODUCT IDENTIFICATION

Product Name	Model/Number	Registration Number
Urine Sediment Analyzer	FUS-100	NL-CA002-2015-37627
	FUS-200	NL-CA002-2015-37626
Urinalysis Hybrid	FUS-1000	NL-CA002-2018-43999
	FUS-2000	NL-CA002-2015-37625
	FUS-3000Plus	NL-CA002-2018-43455

MANUFACTURER

Name of Company	Address	Representative
Dirui Industrial Co., Ltd.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 P.R. China	Li Jing

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/E-mail
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Tel: +31.70.345.8570 Fax: +31.70.346.7299 europe@emergogroup.com

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive

Dirui Industrial Co., Ltd. hereby declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Li Jing

TITLE: Deputy general manager

SIGNATURE:



DATE: July 10th, 2018