



EC DECLARATION OF CONFORMITY



PRODUCT IDENTIFICATION

Product Family Name	Product Name	Registration Number
DIRUI Reagent Strips for Urinalysis	GLUCOSE Reagent Strips for Urinalysis	NL-CA002-2015-37666
	KETONE Reagent Strips for Urinalysis	NL-CA002-2015-37667
	PROTEIN Reagent Strips for Urinalysis	NL-CA002-2015-37665
	2 ITEMS Reagent Strips for Urinalysis (glucose, protein)	NL-CA002-2015-37669
	2 ITEMS Reagent Strips for Urinalysis (glucose, ketone)	NL-CA002-2015-37668
	3 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH)	NL-CA002-2015-37671
	3 ITEMS Reagent Strips for Urinalysis (glucose, protein, ketone)	NL-CA002-2015-37672
	4 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH, blood)	NL-CA002-2015-37674
	4 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH, Specific Gravity)	NL-CA002-2015-37673
	5 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37675
	8 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37676
	9 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37677
	A10	NL-CA002-2015-37678
	E10	NL-CA002-2015-37683
	M10	NL-CA002-2015-37684
	H2-Cr	/
	H8	NL-CA002-2015-37679
	H10	NL-CA002-2015-37680
	H10-800	NL-CA002-2015-37682
	H10-800 (for FUS-2000)	NL-CA002-2015-37681
	H11	NL-CA002-2015-37685
	H11-MA	NL-CA002-2015-37686
	H11-MA(N)	NL-CA002-2015-37687
H11-800	NL-CA002-2015-37688	
H11-800 (for FUS-2000)	NL-CA002-2015-37689	
H11-800MA	NL-CA002-2015-37690	
H11-800MA (for FUS-2000)	NL-CA002-2015-37691	
H12-800MA	NL-CA002-2015-37692	

	H12-800MA (for FUS-2000)	NL-CA002-2015-37693
	H13-Cr	NL-CA002-2015-37694
	H13-Cr (for FUS-2000)	NL-CA002-2015-37643
	H13-800Cr	NL-CA002-2015-37642
	H14-Ca	NL-CA002-2015-37641
	H14-Ca (for FUS-2000)	NL-CA002-2015-37640
	H14-800Ca	NL-CA002-2015-37638
DIRUI FUS series Urinalysis Strips	FUS-10	NL-CA002-2015-37637
	FUS-11	NL-CA002-2015-37636
	FUS-11MA	/
	FUS-12MA	NL-CA002-2015-37635
	FUS-13Cr	NL-CA002-2015-37634
	FUS-14Ca	NL-CA002-2015-37638
FUS- II Urinalysis Strips	FUS-10 II	/
	FUS-11 II	/
	FUS-11MA II	/
	FUS-12MA II	/
	FUS-13Cr II	/
	FUS-14Ca II	/

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: 04/ 2018

