



EC DECLARATION OF CONFORMITY


PRODUCT IDENTIFICATION

Product Name	Model/Number	Registration Number
Reagents and Strips for FUS Series or MUS Series	Sheath	NL-CA002-2018-45401
	Sheath II	
	FE Calibrator II	NL-CA002-2018-45407
	FE Focus B II	
	FE Control II Positive Control	
	FE Control II Negative Control	
	Cleaning liquid II	NL-CA002-2018-45403
	Urine Conductivity Analysis Control	
	Urine Conductivity Analysis Calibrator	
	Cleaning liquid for Refractometer and Turbidimeter	NL-CA002-2015-37538
	H Series urine analyzer Color control-red	NL-CA002-2015-37539
	H Series urine analyzer Color control-green	
	H Series urine analyzer Color control-blue	
	Diluent	NL-CA002-2015-37535
	H Series Control liquid for turbidity	NL-CA002-2015-37540
	H Series Control liquid for specific gravity	NL-CA002-2015-37542
	H Series urine analyzer Calibration liquid for specific gravity	NL-CA002-2015-37543
	H Series urine analyzer Calibration liquid for turbidity	NL-CA002-2015-37541
	Detergent	NL-CA002-2015-37536
	Urinalysis control(Positive)	NL-CA002-2015-37544
Urinalysis control(Negative)		
FUS-II Urinalysis Strips (FUS-10II,FUS-11II,FUS-11MA,FUS-12M AII,FUS-13CrII,FUS-14CaII)	NL-CA002-2018-45402	

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

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CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	Harmonised standards under Directive 98/79/EC for In vitro diagnostic medical devices

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: November 20th, 2018