



EC DECLARATION OF CONFORMITY



PRODUCT IDENTIFICATION

Product Family Name	Product Name		Registration Number
Urine Sediment Analyzer	Kit for Urine Sediment Analyzer	Focus	NL-CA002-2015-37533
		Standard Solution	
		Positive Control	
		Negative Control	
Reagents for H Series Urine Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System	H series urine analyzer Calibration liquid for Specific gravity		NL-CA002-2015-37543
	H series urine analyzer Control liquid for Specific gravity		NL-CA002-2015-37542
	H series urine analyzer Calibration liquid for Turbidity		NL-CA002-2015-37541
	H series urine analyzer Control liquid for Turbidity		NL-CA002-2015-37540
	H series urine analyzer Color control-red		NL-CA002-2015-37539
	H series urine analyzer Color control-green		NL-CA002-2015-37539
	H series urine analyzer Color control-blue		NL-CA002-2015-37539
	FE Calibrator II		NL-CA002-2018-45407
	FE Focus B II		NL-CA002-2018-45407
	FE Control II Positive Control		NL-CA002-2018-45407
	FE Control II Negative Control		NL-CA002-2018-45407
	Urine Conductivity Analysis Control		NL-CA002-2018-45403
	Urine Conductivity Analysis Calibrator		NL-CA002-2018-45403
	Reagents for Urine Analyzer	Urinalysis Control (Positive)	
Urinalysis Control (Negative)			
Reagent for H Series Urine Analyzer, FUS Series Urine Sediment Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System	Urinalysis Multi-Control		NL-CA002-2019-47926
Reagent for FUS Series Urinalysis Hybrid, MUS Series Urinalysis System and H Series Urine Analyzer	Multi-Control for Urine Physical and Chemical Analysis		NL-CA002-2019-48859
	Multi-Calibrator for Urine Physical and Chemical Analysis		NL-CA002-2019-48858
	Urinalysis Control		NL-CA002-2019-48860

Urinalysis Control

NL-CA002-2019-48860

MANUFACTURER

Name of Company	Address	Representative
DIRUI INDUSTRIAL CO., LTD.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 P.R. China	He Haohui

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/E-mail
Emergo Europe B.V.	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands	Tel: +31.70.345.8570 EmergoEurope@ul.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. The above products meet the extension requirements of Regulation EU 2017/746.

Company Representative: He Haohui

Title: Deputy General Manager

Signature: He Haohui

Date: March 3, 2023

