



**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

**Product name : DIRUI Reagent for Urine Analyzer and Urine Sediment Analyzer**

**Model : Urinalysis Control (for Urine Analyzer)**

**H Series Calibration liquid for Specific gravity**

**H Series Control liquid for Specific gravity**

**H Series Calibration liquid for Turbidity**

**H Series Control liquid for Turbidity**

**H Series Color control**

**H Series Cleaning Liquid for Refractometer and Turbidimeter**

**H Series Cleaning liquid (concentrated type)**

**Detergent for Sediment Analyzer**

**Diluent for Sediment Analyzer**

**Sheath for Sediment Analyzer**

**Kit for Urine Sediment Analyzer**

The medical device: /

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 Directive 98/79/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: 长春迪瑞医疗科技股份有限公司



/logotipas/

/CE žyma/

**CE ATITIKTIES DEKLARACIJA**

/CE žyma/

Gamintojo pavadinimas ir adresas: **Dirui Industrial Co., Ltd.**  
**95 Yunhe Street New & High Tech. Development Zone**  
**Changchun, Jilin 130012 Kinijos LR**

Prisiimdami visą atsakomybę, tvirtiname, kad

**Produkto pavadinimas: DIRUI reagentai šlapimo analizatoriui ir šlapimo sedimentų analizatoriui**

**Modelis: Urinalysis Control (for Urine Analyzer)**

**H Series Calibration liquid for Specific gravity**

**H Series Control liquid for Specific gravity**

**H Series Calibration liquid for Turbidity**

**H Series Control liquid for Turbidity**

Medicinos prietaisas: /

**H Series Color control**

**H Series Cleaning Liquid for Refractometer and Turbidimeter**

**H Series Cleaning liquid (concentrated type)**

**Detergent for Sediment Analyzer**

**Diluent for Sediment Analyzer**

**Sheath for Sediment Analyzer**

**Kit for Urine Sediment Analyzer**

Paskirtis: /

**Profesionalus naudojimas**

IVDD klasifikacija: /

**Bendras/Kita**

Žemiau pasirašiusieji tvirtina, jog aukščiau minėta In Vitro diagnostinė medicinos priemonė atitinka pagrindinius reikalavimus, pateikiamus Europos In Vitro diagnostinių medicinos priemonių direktyvos 98/79/EC (IVDD) 1 Priede.

Ši atitikties deklaracija yra grindžiama Europos In Vitro diagnostinių medicinos priemonių direktyvos 98/79/EC III Priedu.

Atitikties įvertinimo procedūra: /

**98/79/EEC I priedas, išskyrus 4 skyrių**

Igaliotas atstovas:

**Emergo Europe**  
**Molenstraat 15 2513 BH Haga**  
**Olandija**

Notifikuotoji įstaiga: /

**TÜV Rheinland LGA Products GmbH**  
**Tillystrasse 2**  
**90431 Nurnberg**  
**Vokietija**  
**CE 0197**

/logotipas/

2015 m.

Changchun, Kinija

Vieta, data /

Atstovas:

/parašas/

Dirui Industrial Co., Ltd. /spaudas/

Pavardė ir pareigos

Tikslus dokumento vertimas į lietuvių kalbą

Vertėja Akvilė Gegelevičienė

Data 2017-09-22

**UAB Diamedica**

Molėtų pl. 73, Vilnius, Lietuva

Tel. 8 5 279 0080



## EC DECLARATION OF CONFORMITY



## PRODUCT IDENTIFICATION

Product Family Name	Product Name	Registration Number
Urinalysis Reagent Strips	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(creatinine, microalbumin)	NL-CA002-2015-37670
	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
	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-CA002-2012-37686
	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(H-800)	NL-CA002-2015-37642
	H13-Cr(for FUS-2000)	NL-CA002-2015-37643
	H13-Cr	NL-CA002-2015-37694
Urinalysis Reagent Strips	H14-Ca(H-800)	NL-CA002-2015-37639
	H14-Ca(FUS-2000)	NL-CA002-2015-37640
	H14-Ca	NL-CA002-2015-37641
	H13-800Cr	NL-CA002-2019-47103
	H14-800Ca	
	H13-800Cr(FUS-2000)	
	H14-800Ca(FUS-2000)	
Urinalysis Strips for Automatic Urine Analyzer	H2-Cr	NL-CA002-2019-47103
	H12-Cr	
	H12-Ca	
	H13-Ca	
	H12-MA	
FUS series Urinalysis Strips	FUS-10	NL-CA002-2015-37638
	FUS-11	NL-CA002-2015-37637
	FUS-11MA	NL-CA002-2015-37636
	FUS-12MA	NL-CA002-2012-25725
	FUS-13Cr	NL-CA002-2015-37635
	FUS-14Ca	NL-CA002-2015-37634
FUS-II series Urinalysis Strips	FUS-10 II	NL-CA002-2018-45402
	FUS-11 II	
	FUS-11MA II	
	FUS-12MA II	
	FUS-13Cr II	
	FUS-14Ca II	
Strips for Urine Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System	FUS-III Urinalysis Strips	NL-CA002-2020-54446

**MANUFACTURER**

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

**AUTHORIZED REPRESENTATIVE**

Name of Company	Address	Telephone/E-mail
Emergo Europe	Prinsessegracht 20 2514 AP The Hague 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.

**Company Representative: Zheng Guoming**

**Title: General manager    Signature:**

**Date: February 5, 2021**



Dirui Industrial Co., Ltd.

DIRUI



## EB ATITIKTIES DEKLARACIJA



## PRODUKTO IDENTIFIKACIJA

Produktų šeimos pavadinimas	Produkto pavadinimas	Registracijos numeris
Šlapimo tyrimų reagentų juostelės	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(creatinine, microalbumin)	NL-CA002-2015-37670
	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
	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-CA002-2012-37686
	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(H-800)	NL-CA002-2015-37642
	H13-Cr(for FUS-2000)	NL-CA002-2015-37643
	H13-Cr	NL-CA002-2015-37694
Šlapimo tyrimų reagentų juostelės	H14-Ca(H-800)	NL-CA002-2015-37639
	H14-Ca(FUS-2000)	NL-CA002-2015-37640
	H14-Ca	NL-CA002-2015-37641
	H13-800Cr	NL-CA002-2019-47103
	H14-800Ca	
	H13-800Cr(FUS-2000)	
	H14-800Ca(FUS-2000)	
Šlapimo tyrimų juostelės automatiniam šlapimo analizatoriui	H2-Cr	NL-CA002-2019-47103
	H12-Cr	
	H12-Ca	
	H13-Ca	
	H12-MA	
FUS serijos šlapimo tyrimų juostelės	FUS-10	NL-CA002-2015-37638
	FUS-11	NL-CA002-2015-37637
	FUS-11MA	NL-CA002-2015-37636
	FUS-12MA	NL-CA002-2012-25725
	FUS-13Cr	NL-CA002-2015-37635
	FUS-14Ca	NL-CA002-2015-37634
FUS-II serijos šlapimo tyrimų juostelės	FUS-10 II	NL-CA002-2018-45402
	FUS-11 II	
	FUS-11MA II	
	FUS-12MA II	
	FUS-13Cr II	
	FUS-14Ca II	
Juostelės šlapimo analizatoriams, FUS serijos Urinalysis Hybrid ir MUS serijos Urinalysis sistemai	FUS-III Urinalysis Strips	NL-CA002-2020-54446

**GAMINTOJAS**

Kompanijos pavadinimas	Adresas	Atstovas
Dirui Industrial Co., Ltd.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 Kinijos LR	Zheng Guoming

**ĮGALIOJAS ATSTOVAS**

Kompanijos pavadinimas	Adresas	Telefonas / e. paštas
Emergo Europe	Prinsessegracht 20 2514 AP The Hague	Tel. +31.70.345.8570 EmergoEurope@ul.com
	Nyderlandai	

**ATITIKTIES ĮVERTINIMAS**

Prietaiso klasifikacija	Atitikties įvertinimo būdas
Klasė – vidinis patvirtinimas	Tarybos direktyvos IVDD 98/79/EB III priedas

Dirui Industrial Co., Ltd. tvirtina, kad aukščiau minimi produktai atitinka reikalavimus, pateikiamus Tarybos direktyvoje 98/79/EB dėl in vitro diagnostinių medicinos prietaisų bei jos perkėlimuose į šalių narių valstybinius įstatymus.

**Kompanijos atstovas:** Zheng Guoming

**Pareigos:** generalinis direktorius

**Parašas:** /parašas/ /spaudas/

**Data:** 2021 m. vasario 5 d.

Tikslus dokumento vertimas į lietuvių kalbą  
Vertėja Akvilė Gegelevičienė  
Data 2021-04-22  
UAB Diamedica  
Gėlių g. 2, Avižieniai, Lietuva