EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION	
Product Name	**Model/Number**
Vaginal Infections Analyzer	GMD-S600

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

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	LVD Directive EMC Directive RoHS Directive Harmonious Standards etc.

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: Jing Li

TITLE: Deputy general manager **SIGNATURE:**

DATE: 4 / 9/ 2017

DIRUI INDUSTRIAL CO., LTD. 迪瑞医疗科技股份有限公司

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

The medical device: /	**Product name :DIRUI FUS Series Urine Sediment Analyzer** **Model : DIRUI FUS-100 Urine Sediment Analyzer** **DIRUI FUS-200 Urine Sediment Analyzer** **DIRUI FUS-2000 Urine Sediment Analyzer**
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 Directive98/79/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 /

DIRUI 迪瑞

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

The medical device: /	**Product name :DIRUI H Series Urine Analyzer** **Model : DIRUI H-50 Urine Analyzer** **DIRUI H-100 Urine Analyzer** **DIRUI H-300 Urine Analyzer** **DIRUI H-500 Urine Analyzer** **DIRUI H-800 Urine Analyzer** **DIRUI H-800(PLUS) Urine Analyzer**
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 Directive98/79/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 /

DIRUI 迪瑞

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

The medical device: /

Product name : DIRUI DR-7000D & CS Series Chemistry Analyzer
Model : DIRUI DR-7000D Semi- Automatic Chemistry Analyzer
DIRUI CS-T240 Auto-Chemistry Analyzer
DIRUI CS-T300 Auto-Chemistry Analyzer
DIRUI CS-300B Auto-Chemistry Analyzer
DIRUI CS-300B(ISE) Auto-Chemistry Analyzer
DIRUI CS-480 Auto-Chemistry Analyzer
DIRUI CS-480 (ISE)Auto-Chemistry Analyzer
DIRUI CS-680 Auto-Chemistry Analyzer
DIRUI CS-680 (ISE)Auto-Chemistry Analyzer
DIRUI CS-400 Auto-Chemistry Analyzer
DIRUI CS-400(ISE) Auto-Chemistry Analyzer
DIRUI CS-600B Auto-Chemistry Analyzer
DIRUI CS-600B(ISE) Auto-Chemistry Analyzer
DIRUI CS-1200 Auto-Chemistry Analyzer
DIRUI CS-1200(ISE) Auto-Chemistry Analyzer
DIRUI CS-1300B Auto-Chemistry Analyzer
DIRUI CS-1300B(ISE) Auto-Chemistry Analyzer
DIRUI CS-1600 Auto-Chemistry Analyzer
DIRUI CS-1600(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000 Auto-Chemistry Analyzer
DIRUI CS-4000-10 Auto-Chemistry Analyzer
DIRUI CS-4000-20 Auto-Chemistry Analyzer
DIRUI CS-4000-30 Auto-Chemistry Analyzer
DIRUI CS-4000-40 Auto-Chemistry Analyzer
DIRUI CS-4000-11(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-12(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-21(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-22(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-31(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-32(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-41(ISE) Auto-Chemistry Analyzer
DIRUI CS-4000-42(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400 Auto-Chemistry Analyzer
DIRUI CS-6400-10 Auto-Chemistry Analyzer
DIRUI CS-6400-20 Auto-Chemistry Analyzer
DIRUI CS-6400-30 Auto-Chemistry Analyzer
DIRUI CS-6400-40 Auto-Chemistry Analyzer
DIRUI CS-6400-11(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-12(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-21(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-22(ISE) Auto-Chemistry Analyzer

DIRUI CS-6400-31(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-32(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-41(ISE) Auto-Chemistry Analyzer
DIRUI CS-6400-42(ISE) Auto-Chemistry Analyzer

Intended purpose: / **Professional use**

IVDD-Classification: / **General IVDs/Self-Certified**

Dirui Industrial Co., Ltd 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.

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive98/79/EC, Annex III.

Conformity assessment procedure: / **Directive 98/79/EEC Annex III**

Authorised representative: / **Emergo Europe**
Prinsessegracht 20 2514 AP The Hague
The Netherlands

Feb.2017

Representalive:

Changchun,China

Place, date /

Dirui Industrial co.,Ltd.

Name and function /

DIRUI 迪瑞

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 Strips for Urinalysis

The medical device: /

Model : DIRUI 1 Item Strip(PRO)
DIRUI 1 Item Strip(GLU)
DIRUI 1 Item Strip(KET)
DIRUI 2 Items Strip(GLU,KET)
DIRUI 2 Items Strip(GLU,PRO)
DIRUI 3 Items Strip(GLU,PRO,PH)
DIRUI 3 Items Strip(GLU,PRO,KET)
DIRUI 4 Items Strip(GLU,PRO,PH,SG)
DIRUI 4 Items Strip(GLU,PRO,PH,BLD)
DIRUI 5 Items Strip
DIRUI 8 Items Strip
DIRUI 9 Items Strip
DIRUI H2-Cr Strip
DIRUI H8 Strip
DIRUI H10 Strip
DIRUI H10-800 Strip
DIRUI H11 Strip
DIRUI H11-MA Strip
DIRUI H11-MA(N) Strip
DIRUI H11-800 Strip
DIRUI H11-800MA Strip
DIRUI H12-800MA Strip
DIRUI H13-Cr Strip
DIRUI H13-800Cr Strip
DIRUI H14-Ca Strip
DIRUI H14-800Ca Strip
DIRUI FUS-10 Strip
DIRUI FUS-11 Strip
DIRUI FUS-11MA Strip
DIRUI FUS-12MA Strip
DIRUI FUS-13Cr Strip
DIRUI FUS-14Ca Strip
DIRUI A10 Strip
DIRUI E10 Strip
DIRUI M10 Strip

Intended purpose: / Professional use

IVDD-Classification: / General IVDs/Self-Certified

DIRUI 迪瑞

Dirui Industrial Co., Ltd 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.

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive98/79/EC, Annex III.

Conformity assessment procedure: / **Directive 98/79/EC Annex III**

Authorised representative: / **Emergo Europe**
Prinsessegracht 20 2514 AP The Hague
The Netherlands

July 2017

Representative:

Changchun,China
Place, date /

Dirui Industrial Co.,Ltd.
Name and function /

EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION		
Product Family Name	**Product Name**	**Model**
Reagents for Vaginal Infections Analyzer	Vaginal Secretions Analysis Strip	GMD-3 GMD-3A GMD-4 GMD-4A GMD-4B GMD-5 GMD-5A GMD-5B GMD-5C GMD-6 GMD-6A GMD-6B GMD-7 GMD-7A GMD-8 GMD-9 GMD-9（N）
	Vaginal Secretions Analysis Control	GMD-9(N) GMD-8 GMD-7（A） GMD-6B GMD-6（A） GMD-5C GMD-5B GMD-5（A） GMD-4B GMD-4（A） GMD-3（A）
	Vaginal Infections Analyzer Detergent	/
	Cell Preservation Liquid	/
	FE Dye	Dye A Dye B
	FE Laminar Liquid	/
	FE Multi Control	Level 1 Level 2 Level 3

	FE Focus B	/
	FE Calibrator	/
	FE Control	Positive Control: Level 1, Level 2, Level 3 Negative Control

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

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	Harmonious Standards etc.

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: Jing Li

TITLE: Deputy general manager **SIGNATURE:**

DATE: 12 / 12/ 2017

EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION		
Product Family Name	**Product Name**	**Registration Number**
Dirui Reagent for Urine Analyzer and Urine Sediment Analyzer	Urinalysis Control (for Urine Analyzer)	NL-CA002-2015-37544
	H Series Calibration liquid for Specific gravity	NL-CA002-2015-37543
	H Series Control liquid for Specific gravity	NL-CA002-2015-37542
	H Series Calibration liquid for Turbidity	NL-CA002-2015-37541
	H Series Control liquid for Turbidity	NL-CA002-2015-37540
	H Series Color control	NL-CA002-2015-37539
	H Series Cleaning Liquid for Refractometer and Turbidimeter	NL-CA002-2015-37538
	H Series Cleaning liquid (concentrated type)	NL-CA002-2015-37537
	Detergent for Sediment Analyzer	NL-CA002-2015-37536
	Diluent for Sediment Analyzer	NL-CA002-2015-37535
	Sheath for Sediment Analyzer	NL-CA002-2015-37534
	Kit for Urine Sediment Analyzer	NL-CA002-2015-37533
	Focus	NL-CA002-2015-37533
	Standard Solution	NL-CA002-2015-37533
	Positive Control	NL-CA002-2015-37533
	Negative Control	NL-CA002-2015-37533
	Urine Conductivity Analysis Control	/
	Urine Conductivity Analysis Calibrator	/

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**	**Standards Applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	Harmonious standards etc.

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