



CE DECLARATION OF CONFORMITY

Manufacturer:

Bioway Biological Technology Co.,Ltd (BW Co.,Ltd)

Add: No.5 Wanshoushan road, Yantai ETDZ, Shandong, China. Tel: 86-516-87989109 Web:www.bioway.com.cn

European Representative:

Shanghai International Holding Corp.GmbH(Europe)

Tel:+49-40-251317 Fax:+49-40-255726

E-mail:shholding@hotmail.com

Add:Eiffestrasse 80.20537 , Hamburg.Germany

DIMDI: DE/0000040627

General applicable directives: In Vitro Directive(IVDD) (98/79/EC)

Product:Urine Analyzer

Brand: Bioway

GMDN: 35918 , 57860

Model:BW-100, BW-200,BW-300, BW-400,BW-500, BW-600,BW-700,BW-701,BW-800, BW-801, BW-900, BW-901

Product: Urine Sediment Analyzer

Brand: Bioway

GMDN:54525

Model:BW-1000, BW-1800,BW-2000, BW-2800,BW-3000

Classification:
Self-Declaration,
IVDD



Other Rule: Annex III
(98/79/EC)

We here declare that the above mentioned products meet the transposition into national law, the provision of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.

Directive(IVDD) (98/79/EC) and the following standards:

IEC 61010-1:2010
AMD1:2016

EN 61326-1:2013
EN 61326-2-6:2013

IEC 61326-1:2012
IEC 61326-2-6:2012

16th June, 2020,
Yantai, Shandong, China

(Date & Place)


(GM Signature & Company Stamp)

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Product Name: Reagent Strips for Urinalysis

Brand: Bioway

Models: URS-1,URS-1C,URS-1K,URS-1V,URS-2C,URS-2K,URS-2M,URS-2P, URS-2V,URS-3, URS-3K,URS-3V, URS-4SG, URS-4H, URS-4V,URS-5K, URS-5V, URS-6,URS-6V,URS-7,URS-7V,URS-8, URS-8A,URS-8GF,URS-8SG,URS-8V,URS-9,URS-9SG,URS-9V,URS-10,URS-10A,URS-10C,URS-10D, URS-10E,URS-10F,URS-10G,URS-10H,URS-10HI,URS-10K,URS-10L,URS-10M,URS-10N,URS-10R, URS-10S,URS-10T,URS-10U,URS-10GF,URS-10MA,URS-10MB,URS-10MC,URS-10V, URS-11, URS-11A,URS-11C,URS-11D,URS-11E,URS-11F,URS-11G,URS-11H,URS-11HI,URS-11K,URS-11L,URS-11M, URS-11N,URS-11R,URS-11T,URS-11U,URS-11EA,URS-11GF,URS-11HA,URS-11HB,URS-11KA, URS-11MA,URS-11MB,URS-11MC,URS-11V, URS-12,URS-12A,URS-12C,URS-12D,URS-12E,URS-12F, URS-12H,URS-12K,URS-12M,URS-12HA,URS-12HB, URS-12V,URS-13,URS-13A,URS-13C,URS-13D, URS-13E,URS-13F,URS-13K,URS-13M,URS-13N,URS-13R,URS-13T,URS-13V, URS-14,URS-14A, URS-14C,URS-14D,URS-14H,URS-14K,URS-14M,URS-14N, URS-14V

General applicable directives: In Vitro Directive(IVDD) (98/79/EC)



Other Rule: Annex III (98/79/EC)

We here declare that the above mentioned products meet the transposition into national law, the provision of the following EC Council Directives and Standards. All supporting documentations are retained under the premise of the manufacturer.

Directive(IVDD) (98/79/EC) and the following standards:

EN ISO 18113-1:2011
 EN ISO 18113-3:2011
 EN ISO 14971:2012
 EN ISO 15223-1:2016

EN 61010-1:2010
 EN 61010-2-101:2002
 EN 61326-1:2013

16th June, 2020,
 Yantai, Shandong, China

(Date & Place)



(GM Signature & Company Stamp)

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E-mail:shholding@hotmail.com Add:Eiffestrasse 80.20537 , Hamburg.Germany

Product: Urine Analyzer Reagents**Brand:** Bioway**GMDN CODE:**54514**Model:**

Cleaning Liquid	URS-400
SG calibration	URS-401
SG QC 1	URS-402
SG QC 2	URS-403
SG QC3	URS-404

SG & Turbidity Cleaning Liquid	URS-405
Urine Analyzer QC (Pos/Neg)	URS-406
Color QC(R,B,G)	URS-407
Turbidity calibration	URS-408
Turbidity QC(1/2)	URS-409
Calibration Liquid	URS-410

Product: Urine Sediment Analyzer Reagents**Brand:** Bioway**GMDN CODE:** 54526**Model:**

Washing Liquid	URS-100
Cleaning Liquid	URS-200
Strong Washing	URS-300
Quality Control (Pos/Neg)	URS-500

Sheath Liquid	URS-600
Diluent Liquid	URS-700
Cleaning Liquid	URS-800
Calibration Liquid	URS-900

General applicable directives: In Vitro Directive(IVDD) (98/79/EC)**Other Rule: Annex III (98/79/EC)**

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Directive(IVDD) (98/79/EC) and the following standards:

EN ISO 18113-1:2011
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 EN ISO 15223-1:2016

EN 61010-1:2010
 EN 61010-2-101:2002
 EN 61326-1:2013

16th June, 2020,
 Yantai, Shandong, China

(Date & Place)



(GM Signature & Company Stamp)



Compliance Report

Applicant: Bioway Biological Technology Co., Ltd
Address: No.5, Wanshoushan road, Yantai etdz, Shandong, China

Product: Urine analyzer, Urine Sediment Analyzer, Reagents For Urine Sediment Analyzer, Reagents For Urine Analyzer, Urine Strips
Type: See annex for details

Product Classification: Others

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02962**
Initial Issue Date: **21 Sep 2018**

Tony Chen

General Manager (Signature)



Annex to Report (No. 02962)

Bioway Biological Technology Co., Ltd

Product Name	Type
Urine Analyzer	BW-100, BW-200, BW-300, BW-400, BW-500, BW-600, BW-700, BW-701, BW-800, BW-801, BW-900, BW-901
Urine Sediment Analyzer	BW-1000, BW-1800, BW-2000, BW-2800, BW-3000
Reagents For Urine Sediment Analyzer	URS-100, UR-200, URS-300, URS-500, URS-600, URS-700, URS-800, URS-900
Reagents For Urine Analyzer	URS-400, URS-401, URS-402, URS-403, URS-404, URS-405, URS-406, URS-407, URS-408, URS-409, URS-410
Urine Strips	URS-1, URS-1C, URS-1K, URS-2C, URS-2K, URS-2M, URS-2P, URS-3, URS-3K, URS-4SG, URS-5K, URS-6, URS-7, URS-8, URS-8A, URS-8GF, URS-8SG, URS-9, URS-9SG, URS-10, URS-10A, URS-10C, URS-10D, URS-10E, URS-10F, URS-10G, URS-10H, URS-10H1, URS-10K, URS-10L, URS-10M, URS-10N, URS-10R, URS-10S, URS-10T, URS-10U, URS-10GF, URS-10MA, URS-10MB, URS-10MC, URS-11, URS-11A, URS-11C, URS-11D, URS-11E, URS-11F, URS-11G, URS-11H, URS-11H1, URS-11K, URS-11L, URS-11M, URS-11N, URS-11R, URS-11T, URS-11U, URS-11EA, URS-11GF, URS-11HA, URS-11HB, URS-11KA, URS-11MA, URS-11MB, URS-11MC, URS-12, URS-12A, URS-12C, URS-12D, URS-12E, URS-12F, URS-12H, URS-12K, URS-12M, URS-12HA, URS-12HB, URS-13, URS-13A, URS-13C, URS-13D, URS-13E, URS-13F, URS-13K, URS-13M, URS-13N, URS-13R, URS-13T, URS-14, URS-14A, URS-14C, URS-14D, URS-14H, URS-14K, URS-14M, URS-14N

This annex is only valid if attached to the report mentioned above.



兹证明

烟台开发区宝威生物技术有限公司

统一社会信用代码: 91370600706320284F

经营地址: 烟台开发区万寿山路 5 号

注册地址: 烟台开发区万寿山路 5 号

的质量管理体系适用于

尿液分析仪、尿沉渣分析系统、尿液分析试纸的生产和销售（许可资质范围内）；尿液分析仪配套试剂、尿沉渣分析系统配套试剂的生产和销售（出口至欧美）

已经 NQA 根据标准

ISO 13485: 2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。

获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询

SNQA 查询网站: www.snqa.com.cn

Managing Director



015

Certificate Number

45664

Date:

03 December 2018

Valid Until:

03 December 2021

EAC Code:

13/19





This is to certify that the Quality Management System of

Bioway Biological Technology Co., Ltd

Unified Social Credit Code : 91370600706320284F

Operation Address : No.5, Wanshoushan Road, Yantai Development Zone, Yantai City, Shandong Province, China

Registered Address : No.5, Wanshoushan Road, Yantai Development Zone, Yantai City, Shandong Province, China

applicable to

Production and Sales of Urine Analyzer, Urine Sediment Analyzer, Urine Strips(within the Scope of License Qualification); Production and Sales of Reagents for Urine Analyzer, Reagents for Urine Sediment Analyzer(Export to Europe and America)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director



015

Certificate Number

45664

Date:

03 December 2018

Valid Until:

03 December 2021

EAC Code:

13/19

