

EC DECLARATION OF CONFORMITY

Doc. No.: IDN – 200103AA

Manufacturer:

Name: Anji SPENQ Industrial Co., Ltd.

Address: F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Tel: 0086-572-5882801 Fax: 0086-572-5676519

EC-Representative:

Name: SUNGO Europe B. V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, The Netherlands

Manufacturing Sites:

F16, Building C, Anji Chamber of Commerce Mansion, No. 99 Tianhuangping South Road, 313300 Anji County, Zhejiang Province, People's Republic of China

Product Names: Urine Container, Stool Container, Petri Dish, Drug Test, Blood Collection Tubes
(The full specification and product list can be found in Appendix I for this document)

Classification of products: In-Vitro Medical Diagnostic Device according to Annex III of the Directive 98/79/EEC. The products bear the mark



The manufacturing process follows the principles of quality assurance as set out in section 4 of 98/79/EC directive.

The products concerned are being manufactured under a quality management system according to Annex III of Directive 98/79/EC.

Compliance of the designated product has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH (ID: 0123)

Ridlerstraße 65, 80339 München, Germany

Certificate No.: Q6 080946 0012 Rev. 01

Issue date: 24.11.2019

Expiry date: 23.11.2022

The above-mentioned declaration of conformity is exclusive under the responsibility of

Anji SPENQ Industrial Co. Ltd.


Declaration person: Li Wenhui

Position: General Manager

Place: Anji City, China

Signature of issue person:

Date: January 23, 2020

安吉鑫洋进出口有限公司
ANJI SPENQ INDUSTRIAL CO., LTD.


APPENDIX I

Appendix I of IDN – 200103AA

The full product list for the EU Declaration of Conformity No. IDN-200103AA is the following:

Product Name	Reference Number	Specification
Urine Container	SR1201	Sterile/Non-Sterile, 30ml
	SR1202	Sterile/Non-Sterile, 40ml
	SR1203	Sterile/Non-Sterile, 60ml
	SR1204	Sterile/Non-Sterile, 120ml
Stool Container	SR1301	Sterile/Non-Sterile, 30ml
	SR1302	Sterile/Non-Sterile, 40ml
	SR1303	Sterile/Non-Sterile, 60ml
	SR1304	Sterile/Non-Sterile, 120ml
Petri Dish	SR16	Sterile/Non-Sterile, 35x15mm
		Sterile/Non-Sterile, 60x15mm
		Sterile/Non-Sterile, 90x15mm
Drug Test	SS1801	Per specification, can include testing for Amphetamine (AMP), Barbituates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Cannabinoids (THC), Methadone (MTD), Methamphetamine (MET), Morphine (MOP), Opiates (OPI), Oxycodone (OXY), Phencyclidine (PCP), D.L-Methylenedioxy-Methamphetamine(MDMA), Methadone Metabolite (EDDP), Nortriptyline (TCA), Propoxyphene (PPX)
Blood Collection Tubes	SR24	Red, 13x75mm, 2/3/4ml, No additive (plain)
		Red, 13x100mm, 5/6/7ml, No additive (plain)
		Red, 16x100mm, 9/10ml, No additive (plain)
		Red, 13x75mm, 2/3/4ml, Clot activator
		Red, 13x100mm, 5/6/7ml, Clot activator
		Red, 16x100mm, 9/10ml, Clot activator
		Blue, 13x75mm, 1.8/2.7ml, PT (3.2% Sodium Citrate)
		Blue, 13x100mm, 4.5ml, PT (3.2% Sodium Citrate)
		Black, 8x120mm, 1.28ml, E.S.R (3.8% Sodium Citrate)
		Black, 13x75mm, 1.6/2.4ml, E.S.R (3.8% Sodium Citrate)
		Gray, 13x75mm, 2/3ml, Sodium Fluoride + Potassium Oxalate (Glucose)
		Gray, 13x100mm, 5ml, Sodium Fluoride + Potassium Oxalate (Glucose)
		Green, 13x75mm, 2/3ml, Lithium Heparin

APPENDIX I

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		Green, 13x100mm, 5ml, Lithium Heparin
		Green, 13x75mm, 2/3ml, Sodium Heparin
		Green, 13x100mm, 5ml, Sodium Heparin
		Purple, 13x75mm, 2/3/4ml, EDTA K2
		Purple, 13x100mm, 5/6/7ml, EDTA K2
		Purple, 13x75mm, 2/3/4ml, EDTA K3
		Purple, 13x100mm, 5/6/7ml, EDTA K3
		Yellow, 13x100mm, 2/3/4/5/6ml, Gel Clot Activator
		Yellow, 16x100mm, 7/8ml, Gel Clot Activator
		Yellow, 13x100mm, 2/3/4/5/6ml, Separate Gel
		Yellow, 16x100mm, 7/8ml, Separate Gel