Declaration of Conformity

Manufacturer：**Guangzhou Improve Medical Instruments Co., Ltd.**
Address： No.102， Kaiyuan Avenue,Science City,Guangzhou Economic & Technological Development District 510530 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

European Representative：Shanghai International Holding Corp. GmbH(Europe)
Address：Eiffestrasse 80, 20537 Hamburg, Germany

Product：Evacuated Blood Collection Tube
Model Code：See attachment
EDMS Code:

Tubes for serum (without anticoagulant)	Tubes with EDTA	Tubes with heparin	Tubes with citrate	Tubes with other anticoagulants
51 01 01 01 00	51 01 01 02 00	51 01 01 03 00	51 01 01 04 00	51 01 01 09 00

Classification(IVD): Other IVDs

Conformity Assessment Route: Annex Ⅲ

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and EC-Representative.

Guangzhou Improve Medical Instruments Co., Ltd *is exclusively responsible for the declaration of conformity.*

DIRECTIVES

General applicable directives:
In Vitro Diagnostic Medical Device Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices (IVD 98/79/EC).

Start of CE Marking: 2004-4-28

Place, Date Guangzhou, 2021-06-05

Signature _____

Chen Hang

Position Management Representative

Attachment

Model Code
IMPROVACUTER® Blood Collection Tube

Items	Tube Size	Volume	Tube material	Additive State	Additive
No Additive Tube	13×100mm	3,4,5,6,7ml	Glass or Plastic	/	/
	13×75mm	3,4,5ml			
	16×100mm	8,9,9.5ml			
	16×125mm	13,14,15ml			
Clot Activator Tube	13×100mm	3,4,5,6,7ml	Glass or Plastic	/	Clot Activator
	13×75mm	3,3.5,4,5ml			
	16×100mm	8,9,9.5ml			
Gel & clot Activator Tube	13×100mm	3,4,5,6ml	Glass or Plastic	/	Gel & clot Activator
	13×75mm	3,3.5ml, 4ml			
	16×100mm	7,8,8.5ml			
ETDA.K2 Tube	13×100mm	3,4,5ml	Glass or Plastic	Liquid or Powder	K_2EDTA
	13×75mm	1,2,3,4,5ml			
	16×100mm	6,7,8,9,10ml			
ETDA.K3 Tube	13×75mm	2,3,4,5ml	Glass or Plastic	Liquid	K_3EDTA
	13×100mm	3,4,5ml			
	16×100mm	6,7,8,9,10ml			
Citrate Tube or Trisodium Citrate（9NC 0.109M）/(9NC 0.129M)	13×100mm	1.8,2.7,3.6,4.5ml	Glass or Plastic	Liquid	0.109mol/L(or0.129mol/L) Buffer sodium citrate
	13×75mm	1.8,2.7,3.6,4.5ml			
	16×100mm	8.1ml			
ESR Tube(4NC 0.109M）/(4NC 0.129M)	13×100mm	1.6,2.4ml	Glass or Plastic	Liquid	0.109mol/L(or0.129mol/L) Buffer sodium citrate
	13×75mm	1.6,2.4ml			
	9×120mm	1.6ml			
Sodium Heparin Tube	13×100mm	2,3,4,5,6ml	Glass or Plastic	Powder	Sodium Heparin
	13×75mm	3,4ml			
	16×100mm	7,8,9,10ml			
Lithium Heparin Tube	13×100mm	2,3,4,5,6ml	Glass or Plastic	Powder	Lithium Heparin
	13×75mm	3,4ml			
	16×100mm	7,8,9,10ml			
Glucose Tube	13×100mm	2,3,4,5,6ml	Glass or Plastic	supersaturated solution	Sodium Fluoride/K2.EDTA
	13×75mm	2,3,4,6ml			
Potassium Oxalate & Sodium Fluoride Tube	13×100mm	2,3,4,5ml	Glass or Plastic	Liquid or Powder	Potassium Oxalate/Sodium Fluoride
	13×75mm	2,3,4ml			
Sodium Fluoride/Na2 EDTA Tube	13×100mm	2,3,4,5ml	Glass or Plastic	Liquid or Powder	Sodium Fluoride/Na2 EDTA
	13×75mm	2,3,4ml			
Gel &EDTA.K2 Tube	13×100mm	4,5,6ml	Glass or Plastic	Powder	Gel & K2EDTA
Gel & Lithium Heparin Tube	13×100mm	4,5,6ml	Glass or Plastic	: Powder	Gel & Lithium Heparin
Gel & Sodium Heparin Tube	13×100mm	4,5,6ml	Glass or Plastic	Powder	Gel & Sodium Heparin
ACD Tube	13×100mm	4,5,6ml	Glass	Liquid	Acid Citrate Dextrose
Cell Free DNA Tube	13×100mm	3,4,5ml	Glass or Plastic	Liquid	EDTA 、Urea、Inositol、Glycine、PBS Buffer
	13×75mm	,2,3,4,5ml			

	16×100mm	6,7,8,9,10ml			
CTC Tube	13×100mm	3,4,5ml	Glass or Plastic	Liquid	EDTA 、Inositol、Glycine、PBS Buffer
	13×75mm	2,3,4,5ml			
	16×100mm	6,7,8,9,10ml			
Blood DNA Tube	13×100mm	3,4,5ml	Glass or Plastic	Liquid	EDTA K2、Gold tricarboxylic acid、Guanidine hydrochloride
	13×75mm	2,3,4,5ml			
	16×100mm	6,7,8,9,10ml			
Blood RNA Tube	13×100mm	3,4,5ml	Glass or Plastic	Liquid	EDTA K2、Gold tricarboxylic acid、Guanidine hydrochloride
	13×75mm	2,3,4,5ml			
	16×100mm	6,7,8,9,10ml			