Declaration of Conformity

Manufacturer: **Guangzhou Improve Medical Instruments Co., Ltd.**
Address: No.102, Kaiyuan Avenue, Science City, Guangzhou Economic & Technological Development District, 510530 Guangzhou, China

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

Product: Evacuated Blood Collection Tube
Model code: See attachment

EDMA Code:

Tubes for serum (without anticoagulant)	Tubes with EDTA	Tubes with heparin	Tubes with citrate	Tubes with other anticoagulants
51 01 10 01	51 01 10 02	51 01 10 03	51 01 10 04	51 01 10 09

Classification: 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).

Standards Applied

EN ISO 13485:2016/AC:2018	EN ISO 14971:2019	EN ISO 6710:2017
EN ISO 11137-1:2015/A2:2019	EN ISO 11137-2:2015	EN ISO 11737-1:2018
EN ISO 11737-2:2020	ISO 15223-1-2021	EN ISO 20417:2021

Start of CE Marking: 2004-4-28

Place, Date of Issue: Guangzhou, 2022-03-25

Signature _____
Name: Chen cheng
Position: Management Representative

Attachment

Model Code

IMPROVACUTER® Evacuated Blood Collection Tube

No.	Additive Type/Model	Specification	Additive & Addition	Photo
1	No Additive Tube	1ml,2ml,3ml,4ml,4.5ml,5ml,6ml,7ml,8ml,9ml,9.5ml,10ml	/	
2	Clot Activator Tube	1ml,2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml,8ml,8.5ml,9ml,9.5ml, 10ml	Clot Activator	
3	Gel & Clot Activator Tube	2ml,3ml,3.5ml,4ml,5ml,6ml,7ml,8ml,8.5ml,9ml	Clot Activator Separator gel	
4	EDTA.K2 Tube	1ml,2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml,8ml,8.5ml,9ml,10ml	EDTA.K2	

5	EDTA.K3 Tube	1ml,2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml, 7.5ml,8ml,9ml,10ml	EDTA.K3	
6	Citrate Tube or Trisodium Citrate (9NC 0.109M)	0.9ml,1.8ml,2.7ml,3.6ml,4.2ml,4.5ml,5.4ml ,6.3ml,7.2ml,8.1ml,2ml,3ml,4ml	0.109mol/L Sodium Citrate	
7	Citrate Tube or Trisodium Citrate (9NC 0.129M)	0.9ml,1.8ml,2.7ml,3.6ml,4.2ml,4.5ml,5.4ml ,6.3ml,7.2ml,8.1ml,2ml,3ml,4ml	0.129mol/L Sodium Citrate	
8	ESR Tube (4NC 0.109M)	1.28ml,1.44ml,1.6ml,2.4ml,3.2ml,4.0ml,4.8 ml,5.6ml,6.4ml,7.2ml,8ml	0.109mol/L Sodium Citrate	
9	ESR Tube (4NC 0.129M)	1.28ml,1.44ml,1.6ml,2.4ml,3.2ml,4.0ml,4.8 ml,5.6ml,6.4ml,7.2ml,8ml	0.129mol/L Sodium Citrate	
10	Sodium Heparin Tube	1ml,2ml,3ml,4ml,5ml,6ml,7ml,8ml,9ml,9.5 ml,10ml	Sodium Heparin	

11	Lithium Heparin Tube	1ml,2ml,3ml,4ml,5ml,6ml,7ml,8ml,9ml,9.5 ml,10ml	Lithium Heparin	
12	Glucose Tube	2ml,3ml,3.5ml,4ml,5ml,6ml	Sodium Fluoride & EDTA.K2	
13	Glucose Tube	2ml,3ml,4ml,5ml	Sodium Fluoride & EDTA.Na2	
14	Fluoride/Oxalate Tube	2ml,3ml,3.5ml,4ml,5ml,6ml	Potassium Oxalate/Sodium Fluoride	
15	Gel & EDTA.K2 Tube	2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml,8ml, 8.5ml,9ml	EDTA.K2 Separator gel	
16	Gel & Lithium Heparin Tube	1ml,2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml, 8ml,8.5ml,9ml	Lithium Heparin Separator gel	

17	Gel & Sodium Heparin Tube	1ml,2ml,3ml,3.5ml,4ml,4.5ml,5ml,6ml,7ml, 8ml,8.5ml,9ml	Sodium Heparin Separator gel	
18	Cell Free DNA Tube	2ml,3ml,4ml,5ml,6ml,7ml,8ml,8.5ml,9ml,10ml	EDTA.K2, Imidazolidinyl Urea, Diazolidinyl Urea, Proclin 300, Glycine	