

EU Declaration of Conformity

Manufacturer: Shandong Chengwu Huabo Medical Equipment Co., Ltd.

Address: No. 3 Yingbin Road, Development of Dangji Town, Chengwu County, Heze City, Shandong Province, China

EC-representative: Sungo Certification Company Limited

Address: Lindenstraße 48-52, 40233 Düsseldorf

Medical Device: Blood Collection Vacuum Tube and Blood Collection needle

Type: Plain, Clot activator, Gel&activator, Sodium fluoride&potassium oxalate, 3,8% Sodium citrate, Lithium heparin, Sodium heparin, EDTAK3, EDTAK2, 3,2% Sodium citrate

Reference Number: see attachment

Brandname: Medicalet

Basic UDI-DI: 06975387351264

Classification: Class A

Conformity Assessment Route: Annex IV, IVDR (EU) 2017/746

We, Shenzhen medicalet Technology Co.,Ltd with our manufacturer Shandong Chengwu Huabo Medical Equipment Co., Ltd. herewith declare in our own responsibility the above-mentioned product meets the provisions of Appendix 9 (EU) Regulation 2017/746 for *in vitro* diagnostic medical devices.

Compliance of the designated product with (EU) Regulation 2017/746 has been assessed and certified by the Notified Body NQA.

The above-mentioned EU Declaration of Conformity is exclusively under the responsibility of manufacturer.

Responsible person

David

Sign and Stamp
06.07. 2022.



深圳市旭丽医疗有限公司
SHENZHEN MEDICALET TECHNOLOGY CO., LTD.

ATTACHMENT

-

-

- **Medicalet Blood Collection Vacuum Tube, type: No additive**

Reference Number:

Cat. No.	Spces	vol	Mateial
Plain Tube			
XL003130750305	13x75	3	PET
XL003130750405	13x75	4	PET
XL003130750505	13x75	5	PET
XL003131000605	13x100	6	PET
XL003131000705	13x100	7	PET
XL003161000805	16x100	8	PET
XL003161000905	16x100	9	PET
XL003161001005	16x100	10	PET
XL003130750300	13x75	3	Glass
XL003130750400	13x75	4	Glass
XL003130750500	13x75	5	Glass
XL003131000600	13x100	6	Glass
XL003131000700	13x100	7	Glass
XL003161000800	16x100	8	Glass
XL003161000900	16x100	9	Glass
XL003161001000	16x100	10	Glass

- **Medicalet Blood Collection Vacuum Tube, type: Clot activator**

Reference Number:

Cat. No.	Spces	vol	Mateial
Clot Activator Tube			
XL004130750305	13x75	3	PET
XL004130750405	13x75	4	PET
XL004130750505	13x75	5	PET
XL004131000605	13x100	6	PET
XL004131000705	13x100	7	PET
XL004161000805	16x100	8	PET
XL004161000905	16x100	9	PET
XL004161001005	16x100	10	PET
XL004130750300	13x75	3	Glass
XL004130750400	13x75	4	Glass
XL004130750500	13x75	5	Glass
XL004131000600	13x100	6	Glass

XL004131000700	13x100	7	Glass
XL004161000800	16x100	8	Glass
XL004161000900	16x100	9	Glass
XL004161001000	16x100	10	Glass

- **Medicalet Blood Collection Vacuum Tube, type: Gel&activator**

Reference Number:

Cat. No.	Spces	vol	Mateial
GEL & COL ACTIVATOR Tube			
XL000130750305	13x75	3	PET
XL000130750405	13x75	4	PET
XL000131000505	13x100	5	PET
XL000131000605	13x100	6	PET
XL000161000705	16x100	7	PET
XL000161000805	16x100	8	PET
XL000161000905	16x100	9	PET
XL000161001005	16x100	10	PET
XL000130750300	13x75	3	Glass
XL000130750400	13x75	4	Glass
XL000131000500	13x100	5	Glass
XL000131000600	13x100	6	Glass
XL000161000700	16x100	7	Glass
XL000161000800	16x100	8	Glass
XL000161000900	16x100	9	Glass
XL000161001000	16x100	10	Glass

- **Medicalet Blood Collection Vacuum Tube, type: Sodium fluoride&potassium oxalate**

Reference Number:

Cat. No.	Spces	vol	Mateial
Glucose Tube			
XL008130750205	13x75	2	PET
XL009130750305	13x75	3	PET
XL009130750405	13x75	4	PET
XL009131000505	13x100	5	PET
XL009131000605	13x100	6	PET
XL008130750200	13x75	2	Glass
XL009130750300	13x75	3	Glass
XL009130750400	13x75	4	Glass
XL009131000500	13x100	5	Glass
XL009131000600	13x100	6	Glass

- **Medicalet Blood Collection Vacuum Tube, type: 3,8% Sodium citrate**

Reference Number:

Cat. No.	Spces	vol	Mateial
ESR Tube			
XL008130750305	13x75	3	PET
XL008130750505	13x75	5	PET
XL008081201600	8x120	1.6	Glass
XL008081201800	8x120	1.8	Glass
XL008130750300	13x75	3	Glass
XL008130750500	13x75	5	Glass

- **Medicalet Blood Collection Vacuum Tube, type: Lithium heparin/sodium heparin**

Reference Number:

Cat. No.	Spces	vol	Mateial
Heparin Tube			
XL005130750205	13x75	2	PET
XL005130750305	13x75	3	PET
XL005130750405	13x75	4	PET
XL005130750505	13x75	5	PET
XL005131000705	13x100	7	PET
XL005161001005	16x100	10	PET
XL006130750305	13x75	3	PET
XL006130750405	13x75	4	PET
XL006130750505	13x75	5	PET
XL006131000705	13x100	7	PET
XL006161001005	16x100	10	PET
XL005130750200	13x75	2	Glass
XL005130750300	13x75	3	Glass
XL005130750400	13x75	4	Glass
XL005130750500	13x75	5	Glass
XL005131000700	13x100	7	Glass
XL005161001000	16x100	10	Glass
XL006130750300	13x75	3	Glass
XL006130750400	13x75	4	Glass
XL006130750500	13x75	5	Glass
XL006131000700	13x100	7	Glass
XL006161001000	16x100	10	Glass

- **Medicalet Blood Collection Vacuum Tube, type: EDTAK2/EDTAK3**

Reference Number:

Cat. No.	Spces	vol	Mateial
EDTA Tube			
XL001130750205	13x75	2	PET
XL001130750305	13x75	3	PET
XL001130750405	13x75	4	PET
XL001130750505	13x75	5	PET
XL001131000605	13x100	6	PET
XL001131000705	13x100	7	PET
XL001161000805	16x100	8	PET
XL001161000905	16x100	9	PET
XL001161001005	16x100	10	PET
XL002130750205	13x75	2	PET
XL002130750305	13x75	3	PET
XL002130750405	13x75	4	PET
XL002130750505	13x75	5	PET
XL002131000605	13x100	6	PET
XL002131000705	13x100	7	PET
XL002161000805	16x100	8	PET
XL002161000905	16x100	9	PET
XL002161001005	16x100	10	PET
XL001130750200	13x75	2	Glass
XL001130750300	13x75	3	Glass
XL001130750400	13x75	4	Glass
XL001130750500	13x75	5	Glass
XL001131000600	13x100	6	Glass
XL001131000700	13x100	7	Glass
XL001161000800	16x100	8	Glass
XL001161000900	16x100	9	Glass
XL001161001000	16x100	10	Glass
XL002130750200	13x75	2	Glass
XL002130750300	13x75	3	Glass
XL002130750400	13x75	4	Glass
XL002130750500	13x75	5	Glass
XL002131000600	13x100	6	Glass
XL002131000700	13x100	7	Glass
XL002161000800	16x100	8	Glass
XL002161000900	16x100	9	Glass
XL002161001000	16x100	10	Glass

- **Medicalet Blood Collection Vacuum Tube, type: 3,2% Sodium citrate**

Reference Number:

Cat. No.	Spces	vol	Mateial
Glucose Tube			
XL008130750205	13x75	2	PET
XL009130750305	13x75	3	PET
XL009130750405	13x75	4	PET
XL009131000505	13x100	5	PET
XL009131000605	13x100	6	PET
XL008130750200	13x75	2	Glass
XL009130750300	13x75	3	Glass
XL009130750400	13x75	4	Glass
XL009131000500	13x100	5	Glass
XL009131000600	13x100	6	Glass

- **Medicalet Micro Blood Collection Vacuum Tube, type: Plain**

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro Plain Tube				
Micro tube	VM003020	8 x 45	0.2	PET
Micro tube	VM003025	8 x 45	0.25	PET
Micro tube	VM003050	8 x 45	0.5	PET
Micro tube	VM003100	8 x 45	1	PET
Micro tube with capillary	VM103020	8 x 45	0.2	PET
Micro tube with capillary	VM103025	8 x 45	0.25	PET
Micro tube with capillary	VM103050	8 x 45	0.5	PET
Micro tube with capillary	VM103100	8 x 45	1	PET

- **Medicalet Micro Blood Collection Vacuum Tube, type: Clot activator**

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro Clot activator Tube				
Micro tube	VM004020	8 x 45	0.2	PET
Micro tube	VM004025	8 x 45	0.25	PET
Micro tube	VM004050	8 x 45	0.5	PET
Micro tube	VM004100	8 x 45	1	PET
Micro tube with capillary	VM104020	8 x 45	0.2	PET
Micro tube with capillary	VM104025	8 x 45	0.25	PET
Micro tube with capillary	VM104050	8 x 45	0.5	PET
Micro tube with capillary	VM104100	8 x 45	1	PET

Medicalet Micro Blood Collection Vacuum Tube, type: Gel & activator

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro GEL & COL ACTIVATOR Tube				
Micro tube	VM005020	8 x 45	0.2	PET
Micro tube	VM005025	8 x 45	0.25	PET
Micro tube	VM005050	8 x 45	0.5	PET
Micro tube	VM005100	8 x 45	1	PET
Micro tube with capillary	VM105020	8 x 45	0.2	PET
Micro tube with capillary	VM105025	8 x 45	0.25	PET
Micro tube with capillary	VM105050	8 x 45	0.5	PET
Micro tube with capillary	VM105100	8 x 45	1	PET

Medicalet Micro Blood Collection Vacuum Tube, type: EDTA k2

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro EDTA k2 Tube				
Micro tube	VM001020	8 x 45	0.2	PET
Micro tube	VM001025	8 x 45	0.25	PET
Micro tube	VM001050	8 x 45	0.5	PET
Micro tube	VM001100	8 x 45	1	PET
Micro tube with capillary	VM101020	8 x 45	0.2	PET
Micro tube with capillary	VM101025	8 x 45	0.25	PET
Micro tube with capillary	VM101050	8 x 45	0.5	PET
Micro tube with capillary	VM101100	8 x 45	1	PET

Medicalet Micro Blood Collection Vacuum Tube, type: EDTA k3

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro EDTA k3 Tube				
Micro tube	VM002020	8 x 45	0.2	PET
Micro tube	VM002025	8 x 45	0.25	PET
Micro tube	VM002050	8 x 45	0.5	PET
Micro tube	VM002100	8 x 45	1	PET
Micro tube with capillary	VM102020	8 x 45	0.2	PET
Micro tube with capillary	VM102025	8 x 45	0.25	PET
Micro tube with capillary	VM102050	8 x 45	0.5	PET

Micro tube with capillary	VM102100	8 x 45	1	PET
---------------------------	----------	--------	---	-----

Medicalet Micro Blood Collection Vacuum Tube, type: Lithium Heparin

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro Lithium Heparin Tube				
Micro tube	VM006020	8 x 45	0.2	PET
Micro tube	VM006025	8 x 45	0.25	PET
Micro tube	VM006050	8 x 45	0.5	PET
Micro tube	VM006100	8 x 45	1	PET
Micro tube with capillary	VM106020	8 x 45	0.2	PET
Micro tube with capillary	VM106025	8 x 45	0.25	PET
Micro tube with capillary	VM106050	8 x 45	0.5	PET
Micro tube with capillary	VM106100	8 x 45	1	PET

Medicalet Micro Blood Collection Vacuum Tube, type: Sodium Heparin

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro Sodium Heparin Tube				
Micro tube	VM007020	8 x 45	0.2	PET
Micro tube	VM007025	8 x 45	0.25	PET
Micro tube	VM007050	8 x 45	0.5	PET
Micro tube	VM007100	8 x 45	1	PET
Micro tube with capillary	VM106020	8 x 45	0.2	PET
Micro tube with capillary	VM106025	8 x 45	0.25	PET
Micro tube with capillary	VM106050	8 x 45	0.5	PET
Micro tube with capillary	VM106100	8 x 45	1	PET

- **Medicalet Micro Blood Collection Vacuum Tube, type: Sodium fluoride&potassium oxalate**

Reference Number:

Product	Cat. No.	Spces	vol	Mateial
Micro Glucose Tube				
Micro tube	VM008020	8 x 45	0.2	PET
Micro tube	VM008025	8 x 45	0.25	PET
Micro tube	VM008050	8 x 45	0.5	PET
Micro tube	VM008100	8 x 45	1	PET
Micro tube with capillary	VM108020	8 x 45	0.2	PET
Micro tube with capillary	VM108025	8 x 45	0.25	PET
Micro tube with capillary	VM108050	8 x 45	0.5	PET
Micro tube with capillary	VM108100	8 x 45	1	PET

- **Medicalet Disposable intravenous blood sample collection needle, Penholder type**

Reference Number:

Cat. No.	Spces	Gauge
CY11618	1.2 x 25 mm	18G
CY11620	0.9 x 25 mm	20G
CY11621	0.8x 25 mm	21G
CY11622	0.7 x 25 mm	22G
CY11623	0.6 x 25 mm	23G
CY11618	1.2 x 25 mm	18G
CY11620	0.9 x 25 mm	20G

- **Medicalet Disposable intravenous blood sample collection needle, Butterfly type**

Reference Number:

Cat. No.	Spces	Gauge
CY11218	1.2 x 28 mm	18G
CY11220	0.9 x 28 mm	20G
CY11221	0.8 x 27 mm	21G
CY11222	0.7 x 25 mm	22G
CY11223	0.6 x 25 mm	23G
CY11224	0.55 x 25 mm	24G
CY11225	0.5 x 16 mm	25G
CY11227	0.4 x 13 mm	27G

- **Medicalet Disposable intravenous blood sample collection needle, Safety Penholder type**

Reference Number:

Cat. No.	Spces	Gauge
SY11618	1.2 x 25 mm	18G
SY11620	0.9 x 25 mm	20G
SY11621	0.8x 25 mm	21G
SY11622	0.7 x 25 mm	22G
SY11623	0.6 x 25 mm	23G

- **Medicalet Disposable intravenous blood sample collection needle holder**

Reference Number:

Cat. No.	Spces	Material
CY133	20 x 55 mm	PP



深圳市旭丽医疗有限公司
SHENZHEN MEDICALET TECHNOLOGY CO., LTD.