

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. **53 23** din 24.08.2023

Solicitantul SC IMUNOTEHNOMED SRL cu sediul str. Gh. Asachi, 42, tel.: 022 811 174,
022 811 197; fax: 022 738 720; e-mail violeta.balan@imunotehnomed.md, solicit înregistrarea în
Registrul de stat al dispozitivelor medicale, următoarele categorii și tipuri de dispozitive medicale
pentru introducerea și punerea la dispoziție pe piață (producător – Anhui Sinic Laboratory Medical
Technology Co., Ltd.):

Nr.	Denumire produs	Model	Tara	Producator
1	Blood Collection Tube	Vacuum tube: EDTA-K3	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
2	Blood Collection Tube	Vacuum tube: No Additives	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
3	Blood Collection Tube	Vacuum tube: SST	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
4	Blood Collection Tube	Vacuum tube: Lithium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
5	Blood Collection Tube	Vacuum tube: Gel + Heparin Lithium	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
6	Blood Collection Tube	Vacuum tube: PT	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
7	Blood Collection Tube	Vacuum tube: ESR	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
8	Blood Collection Tube	Vacuum tube: Glucose	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
9	Blood Collection Tube	Vacuum tube: EDTA-K2	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.

10	Blood Collection Tube	Vacuum tube: Clot Activator	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
11	Blood Collection Tube	Vacuum tube: NaF + EDTA-K2	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
12	Blood Collection Tube	Vacuum tube: Sodium Fluoride	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
13	Blood Collection Tube	Vacuum tube: Sodium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
14	Blood Collection Tube	Vacuum tube: Gel + Sodium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
15	Blood Collection Tube	Vacuum tube: Sodium Citrate	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
16	Blood Collection Tube	Vacuum tube: Gel + Sodium Citrate	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
17	Blood Collection Tube	Vacuum tube: ACD + Gel	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
18	Blood Collection Tube	Vacuum tube: Gel	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
19	Blood Collection Tube	Vacuum tube: Imidazole Alkyl Urea/Glycine/EDTA-K3	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
20	Blood Collection Tube	Micro tube: PT	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
21	Blood Collection Tube	Micro tube: ESR	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
22	Blood Collection Tube	Micro tube: Clot Activator	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
23	Blood Collection Tube	Micro tube: EDTA-K2	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
24	Blood Collection Tube	Micro tube: EDTA-K3	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
25	Blood Collection	Micro tube: Gel	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.

	Tube			
26	Blood Collection Tube	Micro tube: SST	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
27	Blood Collection Tube	Micro tube: Gel + Heparin Lithium	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
28	Blood Collection Tube	Micro tube: Gel + Sodium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
29	Blood Collection Tube	Micro tube: Gel + Sodium Citrate	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
30	Blood Collection Tube	Micro tube: Lithium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
31	Blood Collection Tube	Micro tube: NaF + EDTA-K2	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
32	Blood Collection Tube	Micro tube: Glucose	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
33	Blood Collection Tube	Micro tube: No Additives	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
34	Blood Collection Tube	Micro tube: Sodium Fluoride	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.
35	Blood Collection Tube	Micro tube: Sodium Heparin	China	Anhui Sinic Laboratory Medical Technology Co., Ltd.

Se anexează următoarele acte:

1. Scrisoarea de autorizare de la producător (Anhui Sinic Laboratory Medical Technology Co., Ltd.);
2. Declarația de conformitate CE;
3. Declarația pe propria răspundere privind veridicitatea datelor;
4. Certificat ISO 9001:2015, ISO 13485:2016

Data: 24.08.2023

Semnătura _____

Tablelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	