

SHANGHAI KEHUA BIO-ENGINEERING CO.,LTD

1189 North Qinzhou Road, 200233, Shanghai, PEOPLE'S REPUBLIC OF CHINA

Ngày 20 tháng 05 năm 2025

May 20, 2025

GIẤY XÁC NHẬN TRANG THIẾT BỊ Y TẾ SỬ DỤNG MỘT LẦN
CERTIFICATE OF DISPOSABLE MEDICAL DEVICES

Kính gửi: Bộ Y tế (Vụ Trang thiết bị và Công trình y tế, Các Sở Y tế)

To: Ministry of Health (Department of Medical Device & Contructions; Departments of Health)

Tên: **SHANGHAI KEHUA BIO-ENGINEERING CO.,LTD.**

Địa chỉ: 1189 North Qinzhou Road, 200233, Shanghai, PEOPLE'S REPUBLIC OF CHINA

với tư cách là chủ sở hữu trang thiết bị y tế xác nhận các trang thiết bị y tế dưới đây là trang thiết bị y tế sử dụng một lần

Name: **SHANGHAI KEHUA BIO-ENGINEERING CO.,LTD.**

Address: 1189 North Qinzhou Road, 200233, Shanghai, PEOPLE'S REPUBLIC OF CHINA

as the Product owner of the medical devices, hereby verify that the following medical devices are disposable product:

STT No.	Tên trang thiết bị y tế Product name	Tên viết tắt Short Name	Thông số Specification
1.	Carcinoembryonic Antigen Quantitative Detection KIT (Chemiluminescent Immunoassay)	CEA	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
2.	Ferritin Quantitative Detection KIT (Chemiluminescent Immunoassay)	Ferritin	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Reagent 3:1×17.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
3.	Free Prostate Specific Antigen (fPSA) Detection Kit (Chemiluminescent Immunoassay)	f-PSA	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×6.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
4.	Total Prostate Specific Antigen (t-PSA) Detection Kit (Chemiluminescent Immunoassay)	t-PSA	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×6.0mL, Calibrator A: 1×1.0mL, Calibrator B:1×1.0mL

5.	Cancer Antigen 125 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA125	100 Tests/Kit Reagent 1:1×3.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
6.	Carbohydrate Antigen 19-9 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA19-9	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Reagent 3:1×22.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
7.	Cancer Antigen 15-3 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA15-3	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Reagent 3:1×22.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
8.	CA72-4 Detection Kit (Chemiluminescent Immunoassay)	CA72-4	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control A:1×1.0mL, Control B:1×1.0mL
9.	Pepsinogen I Quantitative Detection KIT (Chemiluminescent Immunoassay)	PG-I	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
10.	Pepsinogen II Quantitative Detection KIT (Chemiluminescent Immunoassay)	PG-II	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
11.	G-17 Quantitative Detection KIT (Chemiluminescent Immunoassay)	G-17	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
12.	Neuron-specific Enolase Quantitative Detection KIT (Chemiluminescent Immunoassay)	NSE	50 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×3.5mL, Reagent 3:1×11mL, Calibrator A:2×1.0mL, Calibrator B:2×1.0mL

13.	Cyfra21-1 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CYFRA21-1	50 Tests/Kit Reagent 1:1×2.5 mL, Reagent 2:1×3.5 mL, Reagent 3:1×8.5 mL, Calibrator A:1×1.0mL, Calibrator B: 1×1.0mL
14.	Squamous-cell Carcinoma Quantitative Detection KIT (Chemiluminescent Immunoassay)	SCCA	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5 mL, Reagent 3:1×8.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1: 1×1.0mL, Control 2: 1×1.0mL
15.	Human Epididymis Protein 4 Quantitative Detection KIT (Chemiluminescent Immunoassay)	HE4	50 Tests/Kit Reagent 1:1×3.5mL, Reagent 3:1×8.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
16.	Human Pro-Gastrin Releasing Peptide Quantitative Detection KIT (Chemiluminescent Immunoassay)	proGRP	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
17.	Thyroid-stimulating Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay)	TSH	100Tests/Kit Reagent1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:2×1.0mL, Calibrator B:2×1.0mL
18.	Total Thyroxine Quantitative Detection KIT (Chemiluminescent Immunoassay)	TT4	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×6.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
19.	Total Triiodothyronine Quantitative Detection KIT (Chemiluminescent Immunoassay)	TT3	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×9.0mL, Reagent 3:1×22.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
20.	Free Thyroxine Quantitative Detection KIT (Chemiluminescent Immunoassay)	FT4	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×6.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL

21.	Free Triiodothyronine Quantitative Detection KIT (Chemiluminescent Immunoassay)	FT3	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Reagent 3:1×22.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
22.	Antibody to Thyroglobulin Quantitative Detection KIT (Chemiluminescent Immunoassay)	Anti-Tg	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A: 1.0mL×1, Calibrator B: 1.0mL×1, Calibrator C: 1.0mL×1, Calibrator D: 1.0mL×1, Calibrator E: 1.0mL×1, Calibrator F: 1.0mL×1
23.	Antibodies to Thyroid Peroxidase Quantitative Detection KIT (Chemiluminescent Immunoassay)	Anti-TPO	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×22.0mL, Calibrator A: 1.0mL×1, Calibrator B: 1.0mL×1, Calibrator C: 1.0mL×1, Calibrator D: 1.0mL×1, Calibrator E: 1.0mL×1, Calibrator F: 1.0mL×1
24.	Thyroglobulin Quantitative Detection KIT (Chemiluminescent Immunoassay)	Tg	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
25.	Procalcitonin Quantitative Detection KIT (Chemiluminescent Immunoassay)	PCT	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
26.	Procalcitonin Quantitative Detection KIT (Chemiluminescent Immunoassay)	PCT	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
27.	Interleukin-6 Quantitative Detection KIT (Chemiluminescent Immunoassay)	IL-6	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×4.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL,

			Control 1:1×1.0mL, Control 2:1×1.0mL
28.	Hepatitis B Surface Antigen Detection KIT (Chemiluminescent Immunoassay)	HBsAg	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:2×1.0mL
29.	Hepatitis B Surface Antibody Quantitative Detection KIT (Chemiluminescent Immunoassay)	Anti-HBs	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:2×1.0mL, Calibrator B:2×1.0mL
30.	Hepatitis B e Antigen Detection KIT (Chemiluminescent Immunoassay)	HBeAg	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL
31.	Hepatitis B e Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-Hbe	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Reagent 3:1×22.0mL, Calibrator A:2×1.0mL
32.	Hepatitis B Core Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-HBc	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×11.0mL, Reagent 3:2×6.0mL, Calibrator A:1×1.0mL
33.	Hepatitis C Virus Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-HCV	100 Tests/Kit Reagent 1:1×3.0mL, Reagent 2:1×7.0mL, Reagent 3:1×12.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
34.	Treponema Pallidum Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-TP	100 Tests/Kit Reagent 1:1×3.0mL, Reagent 2:1×7.0mL, Reagent 3:1×12.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
35.	Human Immunodeficiency Virus Antigen and Antibody Detection KIT (Chemiluminescent Immunoassay)	HIV Ab/Ag	100 Tests/Kit Reagent 1:1×3.0mL, Reagent 2:1×7.0mL, Reagent 3:1×12.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
36.	Insulin Quantitative Detection KIT (Chemiluminescent Immunoassay)	INS	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
37.	Connecting Peptide Quantitative Detection KIT	C-P	100 Tests/Kit Reagent 1:1×5.0mL,

	(Chemiluminescent Immunoassay)		Reagent 2: 1x 7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
38.	N-terminal Pro B-type Natriuretic Peptide Quantitative Detection KIT (Chemiluminescent Immunoassay)	NT-proBNP	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
39.	Beta Human Chorionic Gonadotropin Quantitative Detection KIT (Chemiluminescent Immunoassay)	β-HCG	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
40.	Follicle-stimulating Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay)	FSH	100 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
41.	Luteotropic Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay)	LH	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
42.	Prolactin Quantitative Detection KIT (Chemiluminescent Immunoassay)	PRL	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×12.0mL, Reagent 3: 1×17.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
43.	Progesterone Quantitative Detection KIT (Chemiluminescent Immunoassay)	P	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×7.0mL, Calibrator A: 1×1.0mL, Calibrator B:1×1.0mL
44.	Testosterone Quantitative Detection KIT (Chemiluminescent Immunoassay)	T	100 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×4.5mL, Calibrator A: 1×1.0mL, Calibrator B: 1×1.0mL
45.	Estradiol Quantitative Detection KIT (Chemiluminescent Immunoassay)	E2	100 Tests/Kit Reagent 1: 1×5.0mL, Reagent 2: 1×7.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
46.	Anti-Mullerian Hormone Quantitative Detection KIT (Chemiluminescent Immunoassay)	AMH	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL,

			Control 1:1×1.0mL, Control 2:1×1.0mL
47.	Alpha1-fetoprotein Quantitative Detection KIT (Chemiluminescent Immunoassay)	AFP	100 Tests/Kit Reagent 1:2×5.0mL, Reagent 2:2×3.5mL, Reagent 3:2×11.0mL, Calibrator A:1×1.0mL, Calibrator B: 1×1.0mL
48.	Alpha1-fetoprotein Quantitative Detection KIT (Chemiluminescent Immunoassay)	AFP	50 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×3.5mL, Reagent 3:1×11.0mL, Calibrator A:1×1.0mL, Calibrator B: 1×1.0mL
49.	Carcinoembryonic Antigen Quantitative Detection KIT (Chemiluminescent Immunoassay)	CEA	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
50.	Free Prostate Specific Antigen (fPSA) Detection Kit (Chemiluminescent Immunoassay)	f-PSA	50 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×6.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
51.	Total Prostate Specific Antigen (t-PSA) Detection Kit (Chemiluminescent Immunoassay)	t-PSA	50 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×6.0mL, Calibrator A: 1×1.0mL, Calibrator B:1×1.0mL
52.	Cancer Antigen 125 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA125	50 Tests/Kit Reagent 1:1×1.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
53.	Carbohydrate Antigen 19-9 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA19-9	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Reagent 3:1×11.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
54.	Cancer Antigen 15-3 Quantitative Detection KIT (Chemiluminescent Immunoassay)	CA15-3	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Reagent 3:1×11.0mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
55.	Hepatitis B Surface Antigen Detection KIT (Chemiluminescent Immunoassay)	HBsAg	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL

56.	Hepatitis B Surface Antibody Quantitative Detection KIT (Chemiluminescent Immunoassay)	Anti-HBs	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
57.	Hepatitis B e Antigen Detection KIT (Chemiluminescent Immunoassay)	HBeAg	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL
58.	Hepatitis B e Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-Hbe	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Reagent 3:1×11.0mL, Calibrator A:1×1.0mL
59.	Hepatitis B Core Antibody Detection KIT (Chemiluminescent Immunoassay)	Anti-HBc	50 Tests/Kit Reagent 1:1×5.0mL, Reagent 2:1×11.0mL, Reagent 3:1×6.0mL, Calibrator A:1×1.0mL
60.	N-terminal Pro B-type Natriuretic Peptide Quantitative Detection KIT (Chemiluminescent Immunoassay)	NT-proBNP	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL
61.	D-Dimer Detection Kit (Chemiluminescent Immunoassay)	D-Dimer	50 Tests/Kit Reagent 1: 1×2.5mL, Reagent 2: 1×3.5mL, Calibrator A: 2×0.5mL, Calibrator B:2×0.5mL
62.	Hs-TnI Quantitative Detection Kit (Chemiluminescent Immunoassay)	hs-TnI	50 Tests/Kit Reagent 1:1×2.5mL, Reagent 2:1×3.5mL, Calibrator A:1×1.0mL, Calibrator B:1×1.0mL, Control 1:1×1.0mL, Control 2:1×1.0mL
63.	Washing Buffer of Analytes	Washing Buffer	10 L/Bottle
64.	Washing Buffer	Washing Buffer(concentrated, 25*)	400 mL
65.	Chemiluminescent Substrate	Chemiluminescent Substrate	125 mL×2
66.	Sample Diluent	Sample Diluent	45.0 mL×2
67.	Maintenance Solution	Maintenance Solution	45.0 mL×2
68.	Immunoassay Unassayed Control	Immunoassay QC	Low Value: 1×5.0 mL; High Value: 1×5.0 mL.

69.	Tumor Marker Unassayed Control	Tumor Marker QC	Low Value: 1×2.0 mL; High Value: 1×2.0 mL.
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Người đại diện hợp pháp của Chủ sở hữu

Legal Representative of Product Owner

Ký tên (Ghi họ tên đầy đủ, chức danh)

Xác nhận bằng dấu hoặc chữ ký

(Signature) [full name, title]

(Confirmed with seal or digital signature)


Cao Xiaofen
Deputy general manager

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