


Genrui

≡ **Declaration of Conformity** ≡

Certificate No.: EU2022144

Manufacturer:

Genrui Biotech Inc.
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European Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name:

See attachment

Model:

See attachment

Classification:

Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:

IVDD 98/79/EC Annex III (excludes section 6)

We here with declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

General Applicable Directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016	EN 13612:2002	EN ISO 14971:2012	EN ISO 18113-1:2011
EN 62304:2006	EN 61326-2-6:2013	EN 61010-2-101:2002	EN 61326-1:2013
EN 62366:2008	EN ISO 15223-1:2016	EN 61010-1:2010	EN ISO 18113-3:2011



Place, Date of Issue: Shenzhen, January. 14th, 2022

Position Held in Company Management Representative

Signature: Li Yiping





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Attachment :

Product Name:

Quantitative Immunoassay Analyzer

Model:

FA50, FA120

Including reagents as following:

No.	Kit name	Quality Control name
1	D-Dimer test kit (Immunofluorescence)	D-Dimer Quality Control
2	Glycosylated Hemoglobin (HbA1c) Test Kit (Immunofluorescence)	Glycosylated Hemoglobin (HbA1c) Quality Control
3	β -Human Chorionic Gonadotropin (β -HCG) Test Kit(Immunofluorescence)	β -Human Chorionic Gonadotropin (β -HCG) Quality Control
4	High Sensitive C-Reactive Protein(hs-CRP) Test Kit(Immunofluorescence)	High Sensitive C-Reactive Protein (hs-CRP) Quality Control
5	cTnI/CK-MB/Myo (Cardiac panel) Test Kit (Immunofluorescence)	cTnI/CK-MB/Myo (Cardiac panel) Quality Control
6	N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Test Kit(Immunofluorescence)	N-terminal Pro-brain Natriuretic Peptide (NT-proBNP) Quality Control
7	Myoglobin (Myo) Test Kit (Immunofluorescence)	Myoglobin (Myo) Quality Control
8	Procalcitonin (PCT) Test Kit (Immunofluorescence)	Procalcitonin (PCT) Quality Control
9	Cardiac Troponin I (cTnI) Test Kit (Immunofluorescence)	Cardiac Troponin I (cTnI) Quality Control
10	CK-MB(CK-MB) Test Kit (Immunofluorescence)	CK-MB (CK-MB) Quality Control
11	Interleukin 6 (IL-6) Test Kit (Immunofluorescence)	Interleukin 6 (IL-6) Quality Control
12	C-Reactive Protein (CRP) Test Kit (Immunofluorescence)	C-Reactive Protein (CRP) Quality Control
13	Triiodothyronine (T3) Test Kit (Immunofluorescence)	Triiodothyronine (T3) Quality Control
14	Thyroxine (T4) Test Kit (Immunofluorescence)	Thyroxine (T4) Quality Control



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No.	Kit name	Quality Control name
15	Prostate Specific Antigen (PSA) Test Kit (Immunofluorescence)	Prostate Specific Antigen (PSA) Quality Control
16	Free Prostate Specific Antigen (f-PSA) Test Kit (Immunofluorescence)	Free Prostate Specific Antigen (f-PSA) Quality Control
17	Free Triiodothyronine (FT3) Test Kit (Immunofluorescence)	Free Triiodothyronine (FT3) Quality Control
18	Free Thyroxine (FT4) Test Kit (Immunofluorescence)	Free Thyroxine (FT4) Quality Control
19	Alpha Fetoprotein (AFP) Test Kit (Immunofluorescence)	Alpha Fetoprotein (AFP) Quality Control
20	Carcinoembryonic Antigen (CEA) Test Kit (Immunofluorescence)	Carcinoembryonic Antigen (CEA) Quality Control
21	Thyroid Stimulating Hormone (TSH) Test Kit (Immunofluorescence)	Follicle Stimulating Hormone (FSH) Quality Control
22	CA19-9 Test Kit (Immunofluorescence)	CA19-9 Quality Control
23	CA125 Test Kit (Immunofluorescence)	CA125 Quality Control
24	Dengue NS1 Antigen Test Kit (Immunofluorescence)	Dengue NS1 Antigen Quality Control
25	Malaria Pf/Pv Antigen Test Kit (Immunofluorescence)	Malaria Pf/Pv Antigen Quality Control
26	Serum Amyloid A (SAA) Test Kit (Immunofluorescence)	Serum Amyloid A (SAA) Quality Control
27	Tuberculosis IgG (TB-IgG) Test Kit (Immunofluorescence)	Tuberculosis IgG (TB-IgG) Quality Control
28	Tuberculosis IgM (TB-IgM) Test Kit (Immunofluorescence)	Tuberculosis IgM (TB-IgM) Quality Control
29	Ferritin (FER) Test Kit (Immunofluorescence)	Ferritin (FER) Quality Control
30	Follicle Stimulating Hormone (FSH) Test Kit (Immunofluorescence)	Follicle Stimulating Hormone (FSH) Quality Control
31	Luteinizing Hormone (LH) Test Kit (Immunofluorescence)	Luteinizing Hormone (LH) Quality Control
32	Prolactin (PRL) Test Kit (Immunofluorescence)	Prolactin (PRL) Quality Control


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No.	Kit name	Quality Control name
33	Anti-Müllerian Hormone (AMH) Test Kit (Immunofluorescence)	Anti-Müllerian Hormone (AMH) Quality Control
34	Progesterone (Prog) Test Kit (Immunofluorescence)	Progesterone (Prog) Quality Control
35	Testosterone (Testo) Test Kit (Immunofluorescence)	Testosterone (Testo) Quality Control
36	25-OH Vitamin D (25-OH Vit-D) Test Kit (Immunofluorescence)	25-OH Vitamin D (25-OH Vit-D) Quality Control

