



Certificate

No. Q5 105113 0001 Rev. 02

Holder of Certificate: **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution and Service of In Vitro Diagnostic Medical Devices (including Reagents, Analyzers, Quality Controls, Calibrators and Software) in the areas of Clinical Chemistry, Immunoassay and Molecular Diagnostic**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 105113 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_105113_0001_Rev_02)

Report No.: GZ2013007

Valid from: 2021-04-13

Valid until: 2022-12-31

Date, 2021-04-13



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 105113 0001 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Distribution and Service of
In Vitro Diagnostic Medical Devices including Clinical Chemistry
Reagents, Immunoassay Reagents, Quality Controls, Calibrators
and Software;

Production, Distribution and Service of In Vitro Diagnostic Medical
Devices including Analyzers and Molecular Diagnostic Reagents

Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic
Medical Devices including Analyzers and Molecular Diagnostic
Reagents;

Production of In Vitro Diagnostic Medical Devices for
Immunoassay Reagents



深圳市新产业生物医学工程股份有限公司
Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe)

Letter of authorization

Date: 11st Aug., 2022

We, the undersigned, (Shenzhen New Industries Biomedical Engineering Co., Ltd. (Snibe Co., Ltd.) located at N°16, Jinhui Road, Pingshan New District, Shenzhen, P.R.China) hereby authorize and entitle **Imunotehnomed Ltd, 42 Gh.Asachi str., MD-2028, Chisinau, Republic of Moldova** to import, promote and sell **Maglumi 800, Maglumi 2000, Maglumi X3, Maglumi X8, corresponding reagents, consumables and spare parts from Snibe Co., Ltd.** throughout the territory of the Republic of Moldova.

As the authorized representative, in correspondence with the conditions of Directive 93/42/EEC, 98/79/EEC, 90/385/EEC, Regulation (EU) 2017/746, Imunotehnomed Ltd, shall exercise all powers related to the process of placing medical devices on the market on behalf of Snibe Co., Ltd., in particular, but without limiting the generality of the foregoing, perform registration, renewal or any other variations of the registration with the National Competent Authority.

This authorization of distribution right is valid from the date of issuance to December 31, 2023.

Shenzhen New Industries Biomedical Engineering Co., Ltd.

Ms. Lucy Liu
Vice President
Signature:

Date: 11st Aug., 2022
Code: SQX20220802055

Imunotehnomed Ltd

Mr. Sergiu RATA
Managing Director
Signature:

Date: 11st Aug., 2022

Biossays® Biochemistry/Electrolyte



Biossays® E6

- » Fully-automatic Era of iCa²⁺ Solution
- » Connectable to Total Laboratory Automation System▲



Biossays® 240 Plus

- » Throughput: **240 T/H**
- » ISE: **200 T/H** (Optional)
- » Sample Position: **90**
- » Reagent Position: **90**

Biossays® C8

- » Single module: **1600** tests/hour
- » Four modules combined: **6400** tests/hour
- » ISE module (Optional): **300** tests/hour
- » Capable to integrate with **MAGLUMI® X8*** (High-throughput CLIA analyzer) and decapper module
- » Throughput of Decapper module: Decapper speed: **500** tubes/hour, Capper speed: **400** tubes/hour
- » Reagent compartments: Two trays (**72** positions each)
- » Sample load capacity: **300**

▲ Available soon



Biossays® Biochemistry Test Menu

Cardiac	Hepatic	Lipids	Immune
CK CK-MB α-HBDH LDH Hcy *D-Dimer *LDH1 *ACE *IMA *MYO	TBA ALT (SGPT) AST (SGOT) ALP GGT TBIL DBIL TP ALB *Ammonia *PA *CHE *AFU *5'-NT *Haptoglobin *ADA	HDL-C LDL-C TC TG ApoE ApoA1 ApoB Lp(a) *NEFA	IgM IgA IgG *C3 *C4
Diabetes	Renal	Anemia	Inflammation
GLU LAC HbA1c *GSP *D3-HB *GA	Cr (CREA) Uric Acid Urea Cys-C α1-MG β2-MG mALB *Urine/CSF Protein	Transferrin Fe (Iron) *UIBC *G6PD *Ferritin	CRP (Full Range)
ISE	Inorganic Ion	Rheumatism	Pancreatic
Na ⁺ K ⁺ Cl ⁻ Ca ²⁺ pH	Ca P (phos) Mg <small>NEW</small>	ASO <small>NEW</small> RF <small>NEW</small>	α-AMY LIP <small>NEW</small>

* Available soon



27

Years



146

Countries



181

Parameters



19000

Units Globally



MAGLUMI® X3

- » Throughput: **200 T/H**
- » Sample Position: **72**
- » Reagent Position: **20**
- » Single cup design
- » Space occupied < **0.68 m²**
- » Throughput of per unit area > **294 T/H/m²**



MAGLUMI® X8

- » Throughput: up to **600 T/H** (Single module)
Up to **2400 T/H** (Four modules combined)
- » Sample Position: **300**
- » Reagent Position: **42**
- » Single cup design
- » Capable to link Laboratory Automation system (TLA/LAS)
- » Capable to integrate with **Biossays® C8*** (High-throughput Chemistry analyzer) and decapper module

▲ Available soon

MAGLUMI® Immunossay



MAGLUMI® 600

- » Throughput: **180 T/H**
- » Sample Position: **16**
- » Reagent Position: **4**



MAGLUMI® 800

- » Throughput: **180 T/H**
- » Sample Position: **40**
- » Reagent Position: **9**



MAGLUMI® 2000

- » Throughput: **180 T/H**
- » Sample Position: **144**
- » Reagent Position: **15**
- » Inpeco Automation Track Connectable



MAGLUMI® 2000 PLUS

- » Throughput: **180 T/H**
- » Sample Position: **144**
- » Reagent Position: **25**
- » Inpeco Automation Track Connectable



MAGLUMI® 4000 PLUS

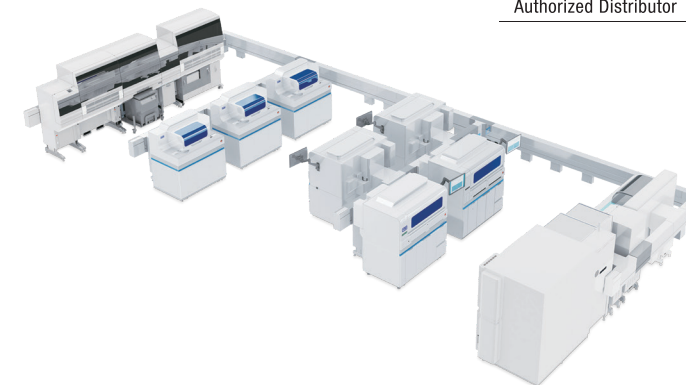
- » Throughput: **280 T/H**
- » Sample Position: **144**
- » Reagent Position: **25**
- » Inpeco Automation Track Connectable

Total Laboratory Automation Solutions

SATLARS™-TCA

thermo
scientific

Authorized Distributor



www.snibe.com
sales@snibe.com

Thyroid

TSH (3rd Generation) FDA
 T4 FDA
 T3 FDA
 FT4 FDA
 FT3 FDA
 Tg (Thyroglobulin)
 TGA (Anti-Tg)
 Anti-TPO
 TRAb
 TMA
 Rev T3
 *T-Uptake

Fertility

FSH
 LH
 HCG/ β -HCG FDA
 PRL (Prolactin)
 Estradiol
 Testosterone
 free Testosterone
 DHEA-S
 Progesterone
 free Estradiol
 17-OH Progesterone
 AMH
 SHBG
 Androstenedione
 *PIGF
 *sFlt-1

Prenatal Screening

AFP (Prenatal Screening)
 Free β -HCG
 PAPP-A
 free Estradiol

Inflammation Monitoring

CRP (High Sensitive)
 PCT (Procalcitonin)
 IL-6 (Interleukin 6)
 SAA (Serum Amyloid A)
 *TNF- α

Kidney Function

β_2 -MG
 Albumin
 *NGAL

TORCH

Toxo IgG
 Toxo IgM
 Rubella IgG
 Rubella IgM
 CMV IgG
 CMV IgM
 HSV-1/2 IgG
 HSV-1/2 IgM
 HSV-1 IgG NEW
 HSV-2 IgG
 *HSV-2 IgM
 *HSV-1 IgM

Cardiac

CK-MB
 Troponin I
 Myoglobin
 hs-cTnl
 H-FABP
 NT-proBNP
 BNP
 D-Dimer
 Lp-PLA2
 MPO NEW
 *HCY

Coagulation Marker

D-Dimer
 *TAT
 *TM
 *PIC
 *tPAIC

Hypertension

Direct Renin
 Aldosterone
 Angiotensin I
 Angiotensin II
 Cortisol
 ACTH

EBV

EBV EA IgG
 EBV EA IgA
 EBV VCA IgG
 EBV VCA IgM
 EBV VCA IgA
 EBV NA IgG
 EBV NA IgA

Tumor Markers

AFP
 CEA
 Total PSA
 f-PSA
 CA 125
 CA 15-3
 CA 19-9
 PAP
 CA 50
 CYFRA 21-1
 CA 242
 CA 72-4
 NSE
 S-100
 SCCA
 TPA-snibe
 ProGRP
 HE4
 HER-2
 PIVKA-II

Glyco Metabolism

C-Peptide
 Insulin
 GAD 65
 Anti-IA2
 ICA
 IAA (Anti Insulin)
 Proinsulin
 *Glucagon
 *ZnT8

Autoimmune

Anti-CCP
 Anti-dsDNA IgG
 ANA Screen
 ENA Screen
 Anti-Sm IgG
 Anti-Rib-P IgG
 Anti-Scl-70 IgG
 Anti-Centromeres IgG
 Anti-Jo-1 IgG
 Anti-M2-3E IgG
 Anti-Histones IgG
 Anti-nRNP/Sm IgG
 Anti-SS-B IgG
 Anti-SS-A IgG
 TGA (Anti-Tg)
 Anti-TPO
 TRAb
 TMA
 ICA
 IAA (Anti Insulin)
 GAD 65
 Anti-IA2
 Anti-MPO NEW
 *ZnT8
 *Anti-Cardiolipin IgG
 *Anti-Cardiolipin IgM
 * β 2-Glycoprotein I IgG
 * β 2-Glycoprotein I IgM

Hepatic Fibrosis

HA
 PIIIP N-P
 C IV
 Laminin
 Cholyglycine
 *GP73

Infectious Disease

HBsAg
 Anti-HBs
 HBeAg
 Anti-HBe
 Anti-HBc
 Anti-HCV
 Syphilis
 Anti-HAV
 HAV IgM
 HIV Ab/Ag Combi
 Chagas
 HTLV I+II
H. pylori IgG
H. pylori IgA
H. pylori IgM
 2019-nCoV IgG
 2019-nCoV IgM
 SARS-CoV-2 S-RBD IgG
 SARS-CoV-2
 Neutralizing Antibody
 SARS-CoV-2 Ag
 *Anti-HBc IgM
 **Chlamydia Pneumoniae* IgG
 **Chlamydia Pneumoniae* IgM
 **Mycoplasma Pneumoniae* IgG
 **Mycoplasma Pneumoniae* IgM

Anemia

Vitamin B12
 Ferritin
 Folate (FA)
 EPO NEW
 *RBC Folate

Metabolism

Pepsinogen I
 Pepsinogen II
 Gastrin-17
 GH (hGH)
 IGF-I
 IGFBP-3

Bone Metabolism

Calcitonin
 Osteocalcin
 25-OH Vitamin D FDA
 Intact PTH
 β -CTx NEW
 total P1NP NEW

Drug Monitoring

Digoxin
 CSA (Cyclosporine A)
 FK 506 (Tacrolimus)

Immunoglobulin

IgM
 IgA
 IgE
 IgG