Immunofluorescence POCT Solution

Multi-Channel Analyzer & Reagents for IVD Manufacturers and Distributors

Guangdong Wesail Biotech Co., Ltd.

◎ Analyzer Features
WS-Mi6000

Rapid

180 T/H, result in 2~8 min for single parameter or 15 min for multi-parameters

Precision

±0.1°C precise temperature control improving test repeatability

Accurate

CV ≤2% between channels, CV ≤5% between analyzers

Display-Friendly

High resolution 11.1" large touch screen provides operational stability and quick response

Compact

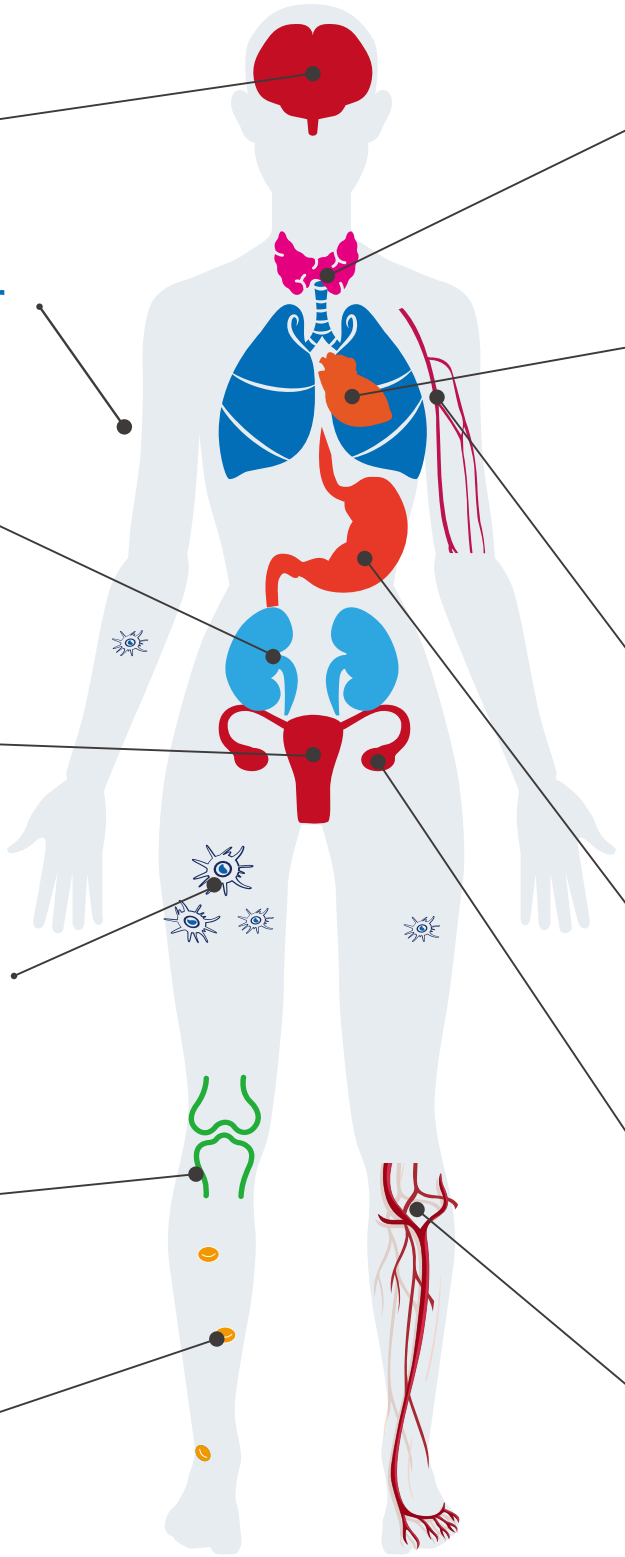
All-in-one analyzer with incubator, barcode reader and thermal printer, no extra step required from cartridge insert to result

◎ Specification - Multi-Channel

Test Speed	180 T/H
Dimension	395.5 × 223.5 × 193 (L x W x H) mm
Weight	≈ 6.4 kg
Display	11-inch Touchscreen
LIS System	Uni or Bi-directional
Data Processor	Intelligence
Sampling	Manual
Barcode Reader	Built-in (external available)
Parameters Import	Barcode
Printer	Built-in Thermal
Incubator	Built-in
Clot and Bubble Detection	No
Auto-dilution	No

Test Menu

Up to 32 tests available with expected expansion to 50 tests



Brain
S100β

Tumor Marker
CEA
AFP
PSA
fPSA ↑

Renal Injury
MAU
NGAL ↑
β2-MG ↑
Cys-C ↑

Pregnancy
β-hCG
FSH
LH
P ↑
PRL ↑
E2 ↑
T ↑
PIGF ↑
sFlt-1 ↑

Inflammation
hs-CRP+CRP
SAA
IL-6
PCT ↑
mPCT ↑

Bone Metabolism
Osteocalcin
25-OH VD

Anemia
Ferritin
Folate ↑
Vitamin B12 ↑

Thyroid
TSH
T4
T3
fT4 ↑
fT3 ↑

Cardiac Marker
hs-cTnI
CK-MB
H-FABP
Myoglobin
cTnI/CK-MB/Myo
ST2
Lp-PLA2
NT-proBNP
BNP

Thrombosis
D-Dimer

Stomach
PG I
PG II

Fertility
AMH
InhB ↑

Diabetes
HbA1c
C Peptide ↑
Insulin ↑

↑ Upcoming

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Cardiac Marker	hs-cTnI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-100.000 ng/mL
	CK-MB	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.200 ng/mL-300.000 ng/mL
	Myoglobin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.80 ng/mL-2000.00 ng/mL
	cTnI/CK-MB/Myo	75 μL	12 mins	S/P/W	20 or 50 Tests/Kit	cTnI 0.200 ng/mL-80.000 ng/mL CK-MB: 2.000 ng/mL-150.000 ng/mL Myo: 10.00 ng/mL-500.00 ng/mL
	H-FABP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.60 ng/mL-512.00 ng/mL
	ST2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 ng/mL-1000.0 ng/mL
	Lp-PLA2	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	7.50 ng/mL-1200.00 ng/mL
	NT-proBNP	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	30 pg/mL-45000 pg/mL
	BNP	60 μL	8 mins	P/W	20 or 50 Tests/Kit	10.0 pg/mL-6000.0 pg/mL
Thrombosis	D-Dimer	60 μL	8 mins	P/W	20 or 50 Tests/Kit	0.150 mg/L FEU-35.000 mg/L FEU
Inflammation	hs-CRP+CRP	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-350.00 mg/L
	SAA	5 μL	2 mins	S/P/W	20 or 50 Tests/Kit	0.50 mg/L-1000.00 mg/L
	IL-6	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	2.0 pg/mL-5000.0 pg/mL
	PCT	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
	mPCT	30 μL	5 mins	S/P/W	20 or 50 Tests/Kit	0.020 ng/mL-200.000 ng/mL
Diabetes	HbA1c	5 μL	5 mins	W	20 or 50 Tests/Kit	3.8 %-18.5 %
Thyroid	TSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.010 μIU/mL-100.000 μIU/mL
	T4	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	5.00 nmol/L-320.00 nmol/L
	T3	60 μL	5 mins	S/P/W	24 or 48 Tests/Kit	0.20 nmol/L-10.00 nmol/L
Pregnancy	β-hCG	5 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.10 mIU/mL-10000.00 mIU/mL
	FSH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.15 mIU/mL-200.00 mIU/mL
	LH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 mIU/mL-200.00 mIU/mL
Fertility	AMH	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.050 ng/mL-23.000 ng/mL

◎ Feature Reagent Performances

Category	Product	Sample volume	Reaction time	Sample	Package	Detection range
Stomach	PGI	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	1.00 ng/mL-200.00 ng/mL
	PGII	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.40 ng/mL-100.00 ng/mL
Tumor Marker	CEA	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.20 ng/mL-1200.00 ng/mL
	AFP	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.60 ng/mL-1210.00 ng/mL
	PSA	60 μL	8 mins	S/P/W	24 or 48 Tests/Kit	0.014 ng/mL-150.000 ng/mL
Renal Injury	MAU	60 μL	2 mins	Urine	20 or 50 Tests/Kit	5.00 mg/L-500.00 mg/L
Bone Metabolism	Osteocalcin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.50 ng/mL-300.00 ng/mL
	25-OH VD	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	3.00 ng/mL-120.00 ng/mL (7.50 nmol/L-300.00 nmol/L)
Anemia	Ferritin	60 μL	8 mins	S/P/W	20 or 50 Tests/Kit	0.5 ng/mL-2000.0 ng/mL

Guangdong Wesail Biotech Co., Ltd.

Address : No.1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, China

Website : http://en.wesailbio.com

E-mail : customer@wesailbio.com

Phone/Fax : 400-900-1339

Version : WS-SPOC-EN-20230719

Linker

Facebook

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	N-terminal pro-Brain Natriuretic Peptide Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	D-Dimer Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	cTnI/CK-MB/Myo Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	Procalcitonin Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	C-Reactive Protein Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards		
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	β-human Chorionic Gonadotropin Test Kit (Immunofluorescence) Model:20 tests/kit, 50 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards		
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen via:
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20214579

Bijlagen
-

Uw aanvraag
5 juli 2021

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 8 juli 2021
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 5 juli 2021 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Guangdong Wesail Biotech Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Glycated Hemoglobin A1c Test Kit (Immunofluorescence)
Pepsinogen I Test Kit (Immunofluorescence)
Pepsinogen II Test Kit (Immunofluorescence)
C Peptide Test Kit (Immunofluorescence)
Insulin Test Kit (Immunofluorescence)
Nucleic Acid Extraction Kit
(geen merknaam) (NL-CA002-2021-61009)
High Sensitivity Cardiac Troponin I Test Kit(Immunofluorescence)
N-terminal pro-Brain Natriuretic Peptide Test Kit(Immunofluorescence)
Heart Type Fatty Acid Binding Protein Test Kit(Immunofluorescence)
Handheld Immunofluorescence Analyzer
Incubator
(geen merknaam) (NL-CA002-2021-61006)
Microalbuminuria Test Kit(Immunofluorescence)
Thyroid Stimulating Hormone Test Kit(Immunofluorescence)
Osteocalcin Test Kit(Immunofluorescence)
Ferritin Test Kit(Immunofluorescence)
Central Nerve Specific Protein 100 β Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61010)
Myoglobin Test Kit(Immunofluorescence)
D-Dimer Test Kit(Immunofluorescence)
Soluble Growth Stimulation Expressed Gene 2 Protein Test Kit(Immunofluorescence)
cTnI/CK-MB/Myo Test Kit(Immunofluorescence)
Myeloperoxidase Test Kit(Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61007)

Procalcitonin Test Kit (Immunofluorescence)
Creatine Kinase Isoenzyme-MB Test Kit (Immunofluorescence)
C-Reactive Protein Test Kit (Immunofluorescence)
Human Serum Amyloid A Test Kit (Immunofluorescence)
Interleukin-6 Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61008)
β-human Chorionic Gonadotropin Test Kit (Immunofluorescence)
Luteinizing Hormone Test Kit (Immunofluorescence)
Anti-Mullerian Hormone Test Kit (Immunofluorescence)
Follicle Stimulating Hormone Test Kit (Immunofluorescence)
(geen merknaam) (NL-CA002-2021-61011)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

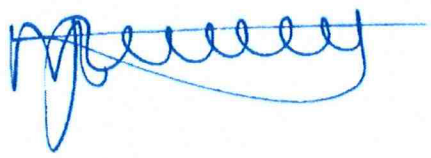
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Guangdong Wesail Biotech Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit).

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

EU DECLARATION OF CONFORMITY

According to Art. 17 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer:	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
Trademark:	WESAIL
SRN:	CN-MF-000008828
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN:	DE-AR-000000087
Product or trade name:	Immunofluorescence Analyzer
Product Model:	WS-Mi6000
Basic UDI-DI :	697384100B600055
Intended Use:	The Immunofluorescence Analyzer should be used along with WESAIL reagents for qualitative or quantitative detection and analysis of human samples to be tested.
Classification acc. to IVDR Ax. VIII:	Class A, rule 5
Applied Standard & Common Specification:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN ISO 15223-1:2021, EN ISO 23640:2015, EN 62366-1:2015, EN IEC 61010-2-081:2020, EN 61010-1:2010+A1:2019, EN IEC 61010-2-010:2020, IEC 61010-2-101:2018, EN IEC 61326-1:2021, EN IEC 61326-2-6:2021
Conformity assessment procedure:	Article 17 + Ax. II + Ax. III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Signed this Day/ 28th of Month/ August of Year/ 2023, Place Dongguan , China

Signature (on behalf of the manufacturer) Dong Yu

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

Devices/Systems/Procedure packs

Search criteria

Manufacturer/Producer (and Authorised Representative) name: WESAIL ✕ **Status:** On the EU market ✕ New search

6 records found.

UDI-DI/ EUDAMED ID	Version	Basic UDI-DI/ EUDAMED DI	Trade name	Risk class	Manufacturer/Producer (and Authorised Representative) name	Actor ID/SRN	Action
06973841000826	1 (Current)	697384100B15004T	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000307	1 (Current)	697384100B600055	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000789	2 (Current)	697384100B100042	Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (MedPath GmbH)	CN-MF-000008828 (DE-AR-000000087)	
06973841000284	1 (Current)	697384100H14006Q	Handheld Colloidalgold Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	
06973841000734	1 (Current)	697384100C60005G	Incubator	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	
06973841000277	1 (Current)	697384100B13004H	Handheld Immunofluorescence Analyzer	Class A	Guangdong Wesail Biotech Co., Ltd. (Lotus NL B.V.)	CN-MF-000008828 (NL-AR-000000121)	

« ‹ 1 › » 25

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Training Certificate

Its hereby certified that

Sergiu Sorocovici
From "GBG-MLD"SRL, has successfully completed all technical training course of Immunofluorescence analyzer Model WS-Mi6000, WS-Si1000 and WS-i60 including installation, Use, Service, Scientific and Technical Support, and is qualified to offer technical support for above mentioned products.

FOR & ON BEHALF OF

广东唯实生物技术有限公司

Guangdong Wesail Biotech Co., Ltd. (WESAIL)

国际营销总监/日期： Vincent NONG

Director of International Sales & Marketing /Date

Company Web：www.wesailbio.com
Company Phone/Fax:：86-769-22890969
Company address：Room 403, Building 1, 1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, 523808, China

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Holder of Certificate: **Guangdong Wesail Biotech Co., Ltd.**
2F, Building 1, 5 Hualian Street
Songshan Lake Science and Technology Industrial Park
Songshan Lake
523808 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunochemistry.**
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

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 108683 0001 Rev. 01

Report No.: GZ2355001 / GZ2355001_CN

Valid from: 2023-10-13
Valid until: 2026-10-12

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 108683 0001 Rev. 01

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):

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Design and Development, Production of In Vitro Diagnostic Reagents for Immunochemistry.
Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry.

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Design and Development, Production and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

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