

Allgemeine Anzeigepflicht gemäß Übergangsvorschrift nach §§ 96 und 96a MPDG mit Verweis auf § 25 MPG sowie Anzeige der verantwortliche Person nach Artikel 15 IVDR (PRRC)

General obligation to notify pursuant to transitional regulations §§ 96 and 96a MPDG with reference to § 25 MPG and notification for the Person Responsible for Regulatory Compliance (PRRC) according to article 15 IVDR

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code DE/CA20		
	Bezeichnung / Name Bezirksregierung Düsseldorf, Dezernat 24		
	Staat / State Deutschland		Land / Federal state Nordrhein-Westfalen
	Ort / City Düsseldorf		Postleitzahl / Postal code 40474
	Straße, Haus-Nr. / Street, house no. Cecilienallee 2		
	Telefon / Phone +49-211-4750		Telefax / Fax +49-211-4752671
	E-Mail / E-mail dez24.mpg@brd.nrw.de		

Anzeige / Notification	
Registrierdatum bei der zuständigen Behörde Registration date at competent authority 26.06.2024	Registriernummer / Registration number DE/CA20/00101140
Rechtsgrundlage / legal basis ☐ In-Vitro-Diagnostika (98/79/EG) / German Medical Device Act (98/79/EG) ☒ Artikel 110(3) Verordnung (EU) 2017/746 (Legacy Device) / Article 110(3) Regulation (EU) 2017/746 (Legacy Device) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)	
Typ der Anzeige / Notification type ☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn DE/CA20/00101140	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG / Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

Anzeigender / Reporting organisation (person)	
Code DE/0000049768	
Bezeichnung / Name Eunitor GmbH	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Düsseldorf	Postleitzahl / Postal code 40476
Straße, Haus-Nr. / Street, house no. Kennedydamm 5	
Telefon / Phone 0211 1587 2276	Telefax / Fax
E-Mail / E-mail info@eunitor.de	

Hersteller / Manufacturer			
Bezeichnung / Name Shenzhen Dymind Biotechnology Co., Ltd.			
Staat / State CN			
Ort / City Shenzhen		Postleitzahl / Postal code 518107	
Straße, Haus-Nr. / Street, house no. 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District			
Telefon / Phone +86 26008015		Telefax / Fax	
E-Mail / E-mail zhouyanping@dymind.com.cn			

Verantwortliche Person für die Einhaltung der regulatorischen Vorschriften gemäß Artikel 15 IVDR (PRRC) Person Responsible for Regulatory Compliance according to article 15 IVDR (PRRC)			
Bezeichnung / Name Shi Yan			
Staat / State Deutschland		Land / Federal state Nordrhein-Westfalen	
Ort / City Düsseldorf		Postleitzahl / Postal code 40476	
Straße, Haus-Nr. / Street, house no. Kennedydamm 5			
Telefon / Phone 0211 1587 2276		Telefax / Fax	
E-Mail / E-mail info@eunitor.de			

Vertreter / Deputy (optional)			
Bezeichnung / Name			
Telefon / Phone		Telefax / Fax	
E-Mail / E-mail			
☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change			

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification ☐ Produkt der Liste A, Anhang II / Device of List A, Annex II ☐ Produkt der Liste B, Anhang II / Device of List B, Annex II ☐ Produkt zur Eigenanwendung / Device for self-testing ☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG ☐ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device Auto Hematology Analyzer
	Produktbezeichnung / Name of device
	Angabe der benutzten Nomenklatur / Nomenclature used ☒ EDMS-Klassifikation / EDMS Classification ☐ GMDN
	Nomenklaturcode / Nomenclature code 23-01
	Nomenklaturbezeichnung / Nomenclature term HAEMOGLOBIN ANALYSER
	Kurzbeschreibung / Short description In Deutsch / In German Hämatologie-Analysator.
Modell:
DP-H10, DP-H12, DP-H13, DP-H15, DP-H16, DP-H17;
DH31, DH33, DH36;
DH20, DH21, DH22, DH23, DH25, DH26;
DH36X, DH33X, DH31X;
DH51, DH53, DH56;
DH51CRP, DH53CRP, DH56CRP, D1-CRP, D3-CRP, D5-CRP;
UN73, UN71, UN76;
DF50, DF51, DF52, DF53, DF55, DF56;
DH71, DH73, DH76;
DH71CRP, DH73CRP, DH76CRP, D2-CRP, D6-CRP, D7-CRP;
DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP;
DM79X, DM78X, DM72X, DM71X, DM75X, DM77X;
DH-600, DH-602, DH-605, DH-610, DH-612, DH-615;
EH590, EH360;
EMATO 4.0.
	In Englisch / In English Hematology Analyzer.
Model:
DP-H10, DP-H12, DP-H13, DP-H15, DP-H16, DP-H17;
DH31, DH33, DH36;
DH20, DH21, DH22, DH23, DH25, DH26;
DH36X, DH33X, DH31X;
DH51, DH53, DH56;
DH51CRP, DH53CRP, DH56CRP, D1-CRP, D3-CRP, D5-CRP;
UN73, UN71, UN76;
DF50, DF51, DF52, DF53, DF55, DF56;
DH71, DH73, DH76;
DH71CRP, DH73CRP, DH76CRP, D2-CRP, D6-CRP, D7-CRP;
DF5-CRP, DF1-CRP, DF3-CRP, DF50CRP, DF52CRP, DF53CRP;
DM79X, DM78X, DM72X, DM71X, DM75X, DM77X;
DH-600, DH-602, DH-605, DH-610, DH-612, DH-615;
EH590, EH360;
EMATO 4.0.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung (Richtlinie 98/79/EG (IVD-Richtlinie)) / Additional information for Annex II and self-testing in vitro diagnostic medical devices (In-vitro-Diagnostic Device Directive 98/79/EK (IVDD))

	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	☐ In übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City

Düsseldorf

Datum
Date

2024-06-26

Name

SHI YAN

Unterschrift
Signature

DECLARATION OF CONFORMITY

MANUFACTURER: Shenzhen Dymind Biotechnology Co., Ltd.
10th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District,
Shenzhen 518107, P. R. China

MEDICAL DEVICE: Product: Auto Hematology Analyzer
Model: DH-600,DH-602,DH-605,DH-610,DH-612,DH-615

CLASSIFICATION: OTHERS, The device is not in IVDD annex II and not for self
testing/performance evaluation.

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Auto Hematology Analyzer STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. EN13612:2002; EN ISO13485:2016; EN ISO 9001:2015; EN ISO14971:2012; EN 61010-1:2010+A1:2019;EN 61010-2-101:2017; EN 61010-2-081:2015; EN 61010-2-010: 2014;EN 61326-1:2020; EN 61326-2-6:2020;ETSI EN 300 330 V2.1.1(2017-02); ETSI EN 301 489-1 V2.2.3(2019-11);ETSI EN 301 489-3 V2.2.1(2019-03);EN 50364: 2018;EN 62369-1: 2009(TEST METHOD);EN ISO 18113-1:2011; EN ISO 18113-3:2011; EN ISO15223-1:2016;EN 591:2001;ISTA 2A:2011.

European Representative: Eunitor GmbH
Kennedydamm 5, 40476 Duesseldorf, Germany

ISSUE DATE: 2021-07-30

PLACE, DATE OF DECLARATION:

SIGNATURE:

SHENZHEN
Pingyi Ren
NAME: PINGYI REN
POSITION: REGULATORY AFFAIR DIRECTOR

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078**

Certificate Holder: **Shenzhen Dymind Biotechnology Co., Ltd.**
Unified Social Credit Code: 91440300071753771K
Registration Address:
10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107
P. R. China
Operation Address:
9th-14th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, 518107
P. R. China

Scope: Design & Development Manufacture and Sales of the Chemistry Analyzer, Auto Hematology Analyzer, Hematology Analyzer, Coagulation Analyzer, Immune Analyzer, Automatic Sample Processing System and In-vitro Diagnostic Reagent (Hematology Analytical Reagent, Immune Analytical Reagent Coagulation Analytical Reagent)
Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-08-28 until 2027-08-27.
It remains valid subject to satisfactory surveillance audits.
First certification 2018
This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2024-08-05


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free Trade Zone), 100176, P. R. China

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078**

No.	Location	Scope
/01	c/o Shenzhen Dymind Biotechnology Co., Ltd. Unified Social Credit Code: 91440300071753771K Registration Address: 10th Floor, Building B, High- tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P. R. China Operation Address: 9th-14th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen P. R. China	Design & Development and Sales of the Chemistry Analyzer, Auto Hematology Analyzer, Hematology Analyzer, Coagulation Analyzer, Immune Analyzer , Automatic Sample Processing System and In-vitro Diagnostic Reagent (Hematology Analytical Reagent, Immune Analytical Reagent, Coagulation Analytical Reagent)
/03	c/o Shenzhen Dymind Biotechnology Co., Ltd. Unified Social Credit Code: 91440300071753771K Registration Address: 10th Floor, Building B, High- tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P. R. China	Manufacture of the In-vitro Diagnostic Reagent (Hematology Analytical Reagent, Immune Analytical Reagent, Coagulation Analytical Reagent)

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078**

Operation Address:
1st, 2nd, 4th Floors, Area A,
Building B, Yeming Mold
Industrial Park,
Genyu Road, Tianliao
Community,
Yutang Subdistrict Office,
Guangming New District,
518132 Shenzhen
P. R. China

/04

c/o Shenzhen Dymind
Biotechnology
Co., Ltd.
Unified Social Credit Code:
91440300071753771K
Registration Address:
10th Floor, Building B, High-
tech
Park, Guangqiao Road, Tianliao
Community, Yutang Street,
Guangming District,
Shenzhen 518107
P. R. China
Operation Address:
Area C of 1st Floor and Area
A,
B and Area C of 6th Floor,
Pepnice Technology Industrial
Park, Tongren Road No. 376,
Yutang Street, Guangming New
District,
Shenzhen,
518132 Guangdong
P. R. China

Manufacture of the Chemistry Analyzer, Auto
Hematology Analyzer, Hematology Analyzer,
Coagulation Analyzer, Immune Analyzer ,
Automatic Sample Processing System

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078**

2024-08-05



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free Trade Zone), 100176, P. R. China

Page 3 of 3

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078/01**

Organization: **Shenzhen Dymind Biotechnology Co., Ltd.**
9th-14th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District, 518107
P. R. China

Site: c/o **Shenzhen Dymind Biotechnology Co., Ltd.**
Unified Social Credit Code: 91440300071753771K
Registration Address:
10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao
Community, Yutang Street, Guangming District, Shenzhen
518107 P. R. China
Operation Address:
9th-14th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District, 518107
P. R. China

Scope: Design & Development and Sales of the Chemistry Analyzer,
Auto Hematology Analyzer, Hematology Analyzer, Coagulation
Analyzer, Immune Analyzer, Automatic Sample Processing
System and In-vitro Diagnostic Reagent (Hematology Analytical
Reagent, Immune Analytical Reagent, Coagulation Analytical
Reagent)

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate
01 100 1833078 from 2024-08-28 until 2027-08-27.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2024-08-05



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room
1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological
Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot
Free Trade Zone), 100176, P. R. China

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078/03**

Organization: **Shenzhen Dymind Biotechnology Co., Ltd.**
9th-14th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District, 518107
P. R. China

Site: **c/o Shenzhen Dymind Biotechnology Co., Ltd.**
Unified Social Credit Code: 91440300071753771K
Registration Address:
10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao
Community, Yutang Street, Guangming District, Shenzhen
518107 P. R. China
Operation Address:
1st, 2nd, 4th Floors, Area A, Building B, Yeming Mold Industrial
Park, Genyu Road, Tianliao Community, Yutang Subdistrict
Office, Guangming New District, 518132 Shenzhen
P. R. China

Scope: Manufacture of the In-vitro Diagnostic Reagent (Hematology
Analytical Reagent, Immune Analytical Reagent, Coagulation
Analytical Reagent)

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate
01 100 1833078 from 2024-08-28 until 2027-08-27.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2024-08-05

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room
1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological
Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot
Free Trade Zone), 100176, P. R. China

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1833078/04**

Organization: **Shenzhen Dymind Biotechnology Co., Ltd.**
9th-14th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District, 518107
P. R. China

Site: **c/o Shenzhen Dymind Biotechnology Co., Ltd.**
Unified Social Credit Code: 91440300071753771K
Registration Address:
10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao
Community, Yutang Street, Guangming District, Shenzhen
518107 P. R. China
Operation Address:
Area C of 1st Floor and Area A, B and Area C of 6th Floor,
Pepnice Technology Industrial Park, Tongren Road No.376,
Yutang Street, Guangming New District, Shenzhen, 518132
Guangdong, P. R. China

Scope: Manufacture of Chemistry Analyzer, Auto Hematology Analyzer,
Hematology Analyzer, Coagulation Analyzer, Immune Analyzer,
Automatic Sample Processing System

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate
01 100 1833078 from 2024-08-28 until 2027-08-27.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2024-08-05



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room
1203, 12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological
Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot
Free Trade Zone), 100176, P. R. China

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2183501-1

Certificate Holder: Shenzhen Dymind Biotechnology Co., Ltd.
10th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District,
Shenzhen 518107
P.R. China

Scope: Design and Development, Manufacture and Distribution of
Sample Processing Systems, Clinical Chemistry Analysers, in-
vitro diagnostic analysers, in-vitro diagnostic test kits, in-vitro
diagnostic reagents, calibrators and controls used in detection
of Specific Proteins, Individual and Specified Hormones /
Proteins, Inflammatory Diseases Markers, Cardiac Markers,
Tumor Markers, Immune Status, Allergy, Thyroid Functions,
Liver function, Auto-Immune Disease, Fertility Testing, Anemia
Related Testing, the analysis of Haematology, and
management of Hemostasis

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies
a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality
management system is subject to yearly surveillance.

Report No.: 10924785-100

Effective date: 2024-10-25

Expiry date: 2026-05-30

Issue date: 2024-10-25

Replaces certificate SX 2183501-1 issued 2024-05-20



Danny Duan

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2183501-1

Certificate Holder: Shenzhen Dymind Biotechnology Co., Ltd.
10th Floor, Building B, High-tech Park, Guangqiao Road,
Tianliao Community, Yutang Street, Guangming District,
Shenzhen 518107
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Shenzhen Dymind Biotechnology Co., Ltd. 10th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China	Administration
/02	c/o Shenzhen Dymind Biotechnology Co., Ltd. 1st, 2nd, 4th Floors, Area A, Building B, Yeming Mold Industrial Park, Genyu Road, Tianliao Community, Yutang Subdistrict Office, Guangming District, Shenzhen 518132 P.R. China	Manufacture of in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls used in detection of Specific Proteins, Individual and Specified Hormones / Proteins, Inflammatory Diseases Markers, Cardiac Markers, Tumor Markers, Immune Status, Allergy, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis
/03	c/o Shenzhen Dymind Biotechnology Co., Ltd. 9th-14th Floor, Building B, High-tech Park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518107 P.R. China	Design and Development and Distribution of Sample Processing Systems, Clinical Chemistry Analysers, in-vitro diagnostic analysers, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls used in detection of Specific Proteins, Individual and Specified Hormones / Proteins, Inflammatory Diseases Markers, Cardiac Markers, Tumor Markers, Immune Status, Allergy, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis
/04	c/o Shenzhen Dymind Biotechnology Co., Ltd. Area C of 1st Floor and Area A, B and Area C of 6th Floor, Pepnice Technology Industrial Park, Tongren Road NO.376, Yutang Street, Guangming District, Shenzhen, 518132 P.R. China	Manufacture of Sample Processing Systems, Clinical Chemistry Analysers, in-vitro diagnostic analysers used in detection Specific Proteins, Individual and Specified Hormones / Proteins, Inflammatory Diseases Markers, Cardiac Markers, Tumor Markers, Immune Status, Allergy, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis

This certificate can be validated on <https://www.certipedia.com>