Certificate

Quality Management System
EN ISO 13485:2016

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 Clinical Chemistry Analysers, and 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, 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.	10922406-100
Effective date	2023-05-31
Expiry date	2026-05-30
Issue date	2023-05-31

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

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

Digitally signed by Bolea Petru
Date: 2026.02.25 14:36:26 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

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Quality Management System
EN ISO 13485:2016

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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	License holder
/02	c/o Shenzhen Dymind Boitechnology Co., Ltd. 1st, 2nd, 4th and 5th Floors, Area A, Building B, Yeming Mold Industrial Park, Genyu Road, Tianliao Community, Yutang Subdistrict Office, Guangming New District, 518132 Shenzhen P.R. China	Manufacture of Clinical Chemistry Analysers, and 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, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis

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The scope of certification also covers the following sites:

/03	c/o Shenzhen Dymind Biotechnology Co., Ltd. 7th-10th Floor, Room 1101,11th Floor, 12th-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 Clinical Chemistry Analysers and 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, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis; Manufacture of Clinical Chemistry Analysers and in-vitro diagnostic analysers used in detection of Specific Proteins, Individual and Specified Hormones / Proteins, Inflammatory Diseases Markers, Cardiac Markers, Tumor Markers, Immune Status, Thyroid Functions, Liver function, Auto-Immune Disease, Fertility Testing, Anemia Related Testing, the analysis of Haematology, and management of Hemostasis

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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Shenzhen Academy of Metrology & Quality Inspection

Certificate

Of

Compliance

No: **WT158000901**

The applicant

Shenzhen Dymind Biotechnology Co., Ltd

4/F, Block A, Sibiono Gene Treatment Area, No.19 Keji Zhongyi Rd., Nanshan District, Shenzhen 518057 P.R.China

has successfully demonstrated that its product

Auto Hematology Analyzer

DF56, DF50, DF51, DF52, DF53, DF55

are compliant with

EN 61326-1: 2013

EN 61326-2-6: 2013

The certificate of compliance shows that the tested sample technically complies with EMC requirement of the European Union **98/79/EC** directive and its latest amended version. The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production.

CE

Authorized Signer:

Issued Date: Nov. 26, 2015

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: DF50, DF51, DF52, DF53, DF55, DF56
CLASSIFICATION:	OTHERS, The device 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/IEC 61010-1:2010;IEC 61010-2-101:2015/EN 61010-2-101:2017; EN/IEC 61010-2-081:2015; EN 61326-1:2013/IEC 61326-1:2012; EN 61326-2-6:2013/IEC 61326-2-6:2012; EN ISO 18113-1:2011; EN ISO 18113-3:2011; EN ISO15223-1:2016.*

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

ISSUE DATE: 2021-7-7

PLACE, DATE OF DECLARATION: *SHENZHEN*

SIGNATURE: Pingyi Ren

NAME: PINGYI REN
POSITION: REGULATORY AFFAIR DIRECTOR