

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shenzhen Dymind Biotechnology
Co., Ltd.**
**2/F, Nanfeng Building B, Nanshan
Yungu Innovation Industrial Park
No. 1183, Liuxian Blvd, Taoyuan Street
Nanshan District
518055 Shenzhen
China**

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-10-18
Certificate Registration No.: SX 60122972 0001
An audit was performed. Report No.: 17051246 006
This Certificate is valid until: 2020-09-03

Certification Body



Date 2017-10-18



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60122972 0001
Report No.: 17051246 006

Organization: Shenzhen Dymind Biotechnology
Co., Ltd.
2/F, Nanfeng Building B, Nanshan
Yungu Innovation Industrial Park
No. 1183, Liuxian Blvd, Taoyuan Street
Nanshan District
518055 Shenzhen
China

Scope: Design and Development, Manufacture and Distribution of
Auto Hematology Analyzers, CPAP Ventilators, Hematology
Analyzer Diluent, Hematology Analyzer Lyse, Cleanser,
C-Reactive Protein Kits (Immunoturbidimetric Method),
C-Reactive Protein Controls and Calibrators;
Manufacture and Distribution of CPAP Masks;
Distribution of Hematology Controls and Calibrators

Sites included:
2/F, Nanfeng Building B, Nanshan Yungu Innovation
Industrial Park, No.1183, Liuxian Blvd, Taoyuan Street,
Nanshan District, Shenzhen 518055, China

Design and Development and Distribution of CPAP Ventilators,
Auto Hematology Analyzers, Hematology Analyzer Diluent,
Hematology Analyzer Lyse, Cleanser, C-Reactive Protein Kits
(Immunoturbidimetric Method), C-Reactive Protein Controls
and Calibrators; Distribution of CPAP Masks,
Hematology Controls and Calibrators

Certification Body



Date: 2017-10-18

S. Liu

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Co., Ltd.
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Yungu Innovation Industrial Park
No. 1183, Liuxian Blvd, Taoyuan Street
Nanshan District
518055 Shenzhen
China

Scope:

Sites included:

No.5-7, 1/F, Block 12, Pingshan Industrial Park,
Taoyuan Street, Nanshan District,
Shenzhen 518055, P.R.China

Manufacture of Hematology Analyzer Diluent,
Hematology Analyzer Lyse, Cleanser, C-Reactive
Protein Kits (Immunoturbidimetric Method), C-Reactive
Protein Controls and Calibrators;

301, Block3B, Nanfeng Building, Nanshan Yungu Innovation
Industrial Park, No.1183, Liuxian Blvd, Taoyuan Street,
Nanshan District, Shenzhen, 518055, P.R.China

Manufacture of Auto Hematology Analyzers,
CPAP Ventilators, CPAP Masks

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Date: 2017-10-18