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: Hematology Analyzer Lyse
Model: LYC-1 ,LYC-2

Product: Hematology Analyzer Diluent
Model: DIL-C

Product: Cleanser
Model: CLE-P

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.

Hematology Analyzer Reagents STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. EN 13612:2002; EN ISO 23640:2015; EN ISO 18113-1:2011; EN ISO 18113-2:2011; ENISO 15223-1:2016; EN ISO 14971:2012; EN ISO 9001:2015; EN ISO 13485:2016.*

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

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: Hematology Calibrator Model: DM-CAL PLUS: 3mL×1、3mL×2、3mL×3 Product: Hematology Control Model: DM-5D: H: 3mL×1、3mL×2、3mL×3 N: 3mL×1、3mL×2、3mL×3 L: 3mL×1、3mL×2、3mL×3 Control set: 3mL (H) ×1, 3mL (N) ×1, 3mL (L) ×1
CLASSIFICATION:	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.

Reagents STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*
EN ISO13485:2016;ENISO 9001:2015;ENISO 14971:2012;ENISO18113-1:2011; ENISO18113-2:2011; ENISO15223-1:2016; EN13612:2002; ENISO23640:2015.

EUROPEAN REPRESENTATIVE: Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg, Germany

ISSUE DATE: 2020-09-24

PLACE, DATE OF DECLARATION: *SHENZHEN,*

SIGNATURE: Pingyi Ren

NAME: PINGYI REN
POSITION: REGULATORY AFFAIR DIRECTOR