

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: Class A
Basic UDI-DI: 6970493090801010NW

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

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the Regulation (EU) 2017/746 Annex VIII, rule 5. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied: see attached list of (harmonised - EN) standards for which documented evidence of compliance can be provided.

EN ISO 13485-2016;	EN ISO 14971-2019;	EN 62366-1:2015
EN ISO18113-1-2011;	EN ISO18113-2-2011;	EN ISO15223-1-2016;
EN ISO 23640-2015;	EN 13612- 2002	

Place of Declaration: Shenzhen Date: 2022.05.20



Name: Pingyi Ren

Position: Regulatory Affair Director

Signature:

