

EU DECLARATION OF CONFORMITY

According to In vitro diagnostic Regulation (EU) 2017/746

Manufacturer:

DLAB Scientific Co., Ltd.
YuAn Road 31, Airport Economic Core Zone, Shunyi
District, Beijing 101318, China

SRN:

CN-MF-000025396

European Representative:

Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherlands

SRN:

NL-AR-000002066

Product Name:

High Speed Centrifuge

Product Model and Basic UDI-DI

Product Model	Basic UDI-DI
D1008	697548995HB161AARU
D2012Plus	697548995LP161AAZN
D1524R	697548995LK181AAY3
D1524	697548995QD232AAXA
D1524C	697548995QD232ABXC
D3024	697548995LW161AA4L
DM1424	697548995LM161AAYF
DM1224	697548995LI181AAX9
D1012UA	697548995UC229AAZV
D2012S	697548995LV229AA4W
DG1616	697548995QC232AAWV
DG1616R	697548995QB232AAWG
DG1616RE	697548995QB232ABWJ

Classification:

Class A, according to Rule 5a of IVDR Annex VIII

Applied Standards:

EN ISO 13485:2016/A11:2021; EN ISO 15223-1:2021/A1:2025; EN ISO 14971:2019/A11:2021; EN ISO 18113-1:2024; EN 62366-1:2015/A1:2020 EN IEC 61326-2-6:2021; EN IEC 61010-2-101:2022/A11:2022

Conformity assessment procedure: Annex IV

According to Annex II and Annex III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the In vitro diagnostic Regulation (EU) 2017/746. All supporting documentations are retained under the premises of the manufacturer.

Signature:

Name/Position: Guo Lei /GM

Date: 2025/12/3

Place: Bei Jing / China