

# EC 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, Netherland

**SRN:**

NL-AR-000002066

**Product Name:**

Low Speed Centrifuge

**Product Model**

DM0412, DM0412 (A6-50P), DM0506, DM0408,  
DM0424, DM0636, DM0306, Q0436E, Q0408E,  
DM0436E

**Basic UDI-DI**

697548995LD161AAUS

**Classification:**

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

**Applied Standards:**

EN ISO 13485:2016/A11:2021; EN ISO 15223-1:2021;  
EN ISO 14971:2019/A11:2021; EN ISO 18113-1:2011;  
EN 62366-1:2015; EN 61326-2-6:2006;  
EN 61010-2-101:2002

**Conformity assessment procedure:**

Annex IV

According to Annex II and Annex III of TD

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:** 2023/09/08

Place: Bei Jing / China