

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