EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: Hangzhou Bosure Biotech Co., Ltd.

Address: 3rd Floor, Building 1, No. 1418-25 Moganshan Road, Hangzhou, China

Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product/s	Model
BioAid® Lipid Testing System	LP-101, LP-102

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity Assessment Route: Annex III,except Point 6,of Directive

Applicable Standards:

EN ISO 13485:2016, EN 13612:2002, EN 13975:2003, EN ISO 14971:2012, EN 15193:2009, EN 15194:2009, EN ISO 15223-1:2021, EN 17511:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 61010-1:2010, EN 61010-2-101:2017, EN 61326-1:2013, EN 61326-2-6:2013, EN 62366-1:2015, EN 62304:2006

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

2022.03.20 Hangzhou

(Place and date of issue)

杭州博旭生物技术有限公司

HANGZHOU BOSURE BIOTECH CO.,LTD

Vivi Wang

Vivi Wang

Quality Manager