Declaration of Conformity

No. ZYIN2021048

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

EC Representative

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Product Name

Mass Spectrometry System

Model and Specification

EXS2000, EXS2600, EXS3000, EXS3600

Including the reagents as following:

See the attachment

Product Classification

Others device, not in annex II and not for self-testing, not for performance evaluation

Conformity Assessment Route

IVDD 98/79/EC Annex III (excludes section 6)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices, and they are with both Directive 2011/65/EU of the European Parliament and of the Council of 8 Jun 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive

2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment. All supporting documentations are retained at the premises of the manufacturer.

General applicable directive

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment.

Standards Applied

EN ISO 13485:2016	EN ISO 9001:2015	EN ISO 14971:2019
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
EN ISO 15223-1:2016	EN 62304:2006/A1:2015	IEC 61010-1:2010/AMD1:2016
EN IEC 63000:2018	IEC 61010-2-101:2018	IEC 61326-1:2012
EN 61326-2-6:2012	EN ISO 23640:2015	EN ISO 17511:2003
EN 13612:2002		

CE

Place	Chongqing, China
Date of Issue	2021-07-26
Version	02
Signature:	
Name of Authorized Signatory:	Guo Yongli
Position:	Management Representative

