EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVD Devices of NOT Annex Ⅱ and NOT self-test)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence) REF No.: BA0010 Model: 20 tests/kit
Basic UDI-DI	697384100A00103K
UDI-DI	6973841000857
Intended Use	This kit applies to the quantitative determination of cardiac troponin I (cTnI) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of acute myocardial infarction in clinic.
GMDN Code	54010
EMDN Code	W0102160703
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive

Applicable Standards			
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
	EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
	EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
	ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

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.

Signed this Day/ 30th of Month/ June of Year/ 2021, Place (Dongguan), China

Signature (on behalf of the manufacturer)

Name of authorized signatory: **Dong Yu**

Position held in the company: **General Manager**

Company Seal/Stamp:

EU DECLARATION OF CONFORMITY

According to Art. 17 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Manufacturer:	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
Product or trade name:	Immunofluorescence Analyzer
Product Model	WS-Si1500
Basic UDI-DI	697384100B15004T
UDI-DI	6973841000826
Intended Use	The instrument is used in conjunction with WESAIL reagents and is used for qualitative or quantitative and quantitative analysis of human samples to be tested.
GMDN Code	48014
EMDN Code	W0201020103
Classification acc. to IVDR Ax. VIII:	Class A, rule 5
Applied Standard & Common Specification:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 13612:2002, EN ISO 15223-1:2021, EN ISO 23640:2015, EN 62366-1:2015, IEC 61010-2-101:2018, EN IEC 61326-1:2021, EN IEC 61326-2-6:2021
Conformity assessment procedure:	Article 17 + Ax. II + Ax. III
CE certificate No.:	N.A.

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

Signed this Day/ 15th of Month/ January of Year/ 2021, Place Dongguan , China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Holder of Certificate: **Guangdong Wesail Biotech Co., Ltd.**
2F, Building 1, 5 Hualian Street
Songshan Lake Science and Technology Industrial Park
Songshan Lake
523808 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunochemistry.**
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 108683 0001 Rev. 01

Report No.: GZ2355001 / GZ2355001_CN

Valid from: 2023-10-13
Valid until: 2026-10-12

Date, 2023-09-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 108683 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Guangdong Wesail Biotech Co., Ltd.
2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic Reagents for Immunochemistry.
Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry.

Guangdong Wesail Biotech Co., Ltd.
Room 201, Building 10, 19 Alishan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Servicing of In Vitro Diagnostic Instruments for Immunochemistry.

Digitally signed by Ceaicovschi Tudor
Date: 2025.10.16 08:53:00 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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