BOSON

Declaration of Conformity

Manufacturer	Xiamen Boson Biotech Co,. Ltd. 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian 361021, P. R. China.
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product	Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-2 Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-4 Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-6
Classification	Self-Test IVD
Confirmaty Assessment Route	Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III section 6

We herewith declare that above mentioned products meet the provisions of the council Directive 98/79/EC for medical devices. All Supporting Documentation is Retained under the premises of the manufacturer. We have sole responsibility for issuing the Declaration of Conformity.

Standard Applied	ISO 13485:2016	EN ISO 14971:2012
	EN ISO 18113-1:2011	EN ISO 18113-4:2011
	ISO 15223-1:2016	EN 62366-1:2015
	EN 13612:2002	EN ISO 23640:2015

Notified Body	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany. Identification number: 0123
(EC) Certificate(s)	No. V9 061317 0006 Rev. 00
Start of CE-Marking	2021-04-01
Place, Date of Issue	Xiamen, 2021-04-01
Signature	Changgong Zhang (Signed By Boson Representative) Name: Changgong Zhang Title: General Manager

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Declaration of Conformity

Manufacturer	Xiamen Boson Biotech Co,. Ltd. 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian 361021, P. R. China.
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product	Rapid SARS-CoV-2 Antigen Test Card REF: 1N40C5-2, 1N40C5-4, 1N40C5-6 1N40C5-7, 1N40C5-8, 1N40C5-9, 1N40C5-10
Classification	Self-Test IVD
Confirmaty Assessment Route	Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III section 6

We herewith declare that above mentioned products meet the provisions of the council Directive 98/79/EC for medical devices. All Supporting Documentation is Retained under the premises of the manufacturer. We have sole responsibility for issuing the Declaration of Conformity.

Standard Applied	EN ISO 13485:2016	EN ISO 14971:2019
	EN ISO 18113-1:2011	EN ISO 18113-4:2011
	ISO 15223-1:2021	EN 13641:2002
	EN 13612:2002	EN ISO 23640:2015
	IEC 62366-1:2015	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany. Identification number: 0123	
(EC) Certificate(s)	No. V9 061317 0006 Rev. 01	
Start of CE-Marking	2021-04-01	
Place, Date of Issue	Xiamen, 2022-06-23	
Signature	Changgong Zhang (Signed By Boson Representative) Name: Changgong Zhang Title: General Manager	

CE
0123

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 061317 0006 Rev. 01

Manufacturer: **Xiamen Boson Biotech Co., Ltd.**
90-94 Tianfeng Road
Jimei North Industrial Park
361021 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Product: **In Vitro diagnostic devices for self testing**

Model(s): **Rapid SARS-CoV-2 Antigen Test Card**

Parameters:

Model Name:	Model No.:
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-2
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-4
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-6
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-7
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-8
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-9
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-10

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. 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:V9 061317 0006 Rev. 01

Report No.: SH21075CN02

Valid from: 2021-11-12
Valid until: 2024-05-26

Date, 2021-11-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 061317 0006 Rev. 00

Manufacturer:

Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road
Jimei North Industrial Park
361021 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Product: **In Vitro diagnostic devices for self testing**

Model(s): **Rapid SARS-CoV-2 Antigen Test Card**

Parameters:

Model Name:	Model No.:
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-2
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-4
Rapid SARS-CoV-2 Antigen Test Card	REF 1N40C5-6

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. 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:V9 061317 0006 Rev. 00

Report No.: 713210321

Valid from: 2021-04-01
Valid until: 2022-05-26

Date, 2021-04-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park,
361021 Xiamen, Fujian,
People's Republic of China

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
061317	713312198 SH2407500_CLI	- medical_devices@tuvsud.com	-	2024-09-30	1 of 3

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 061317 0008 Rev. 00

Reference: 713312198 | SH2407500_CLI

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 (in the following referenced as IVDR) as regards the transitional provisions for certain in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under IVDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the above stated manufacturer with the following Single Registration Number (SRN)

Single Registration Number: CN-MF-000001096

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive or these devices did not require a Notified Body certificate under Directives.

If devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26. May 2022 and before 09. July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110 (3c) of IVDR, are shown below:

- 31. December 2027, for devices certified under IVDD
- 31. December 2027, for class D devices;
- 31. December 2028, for class C devices;
- 31. December 2029, for class B devices and for class A devices placed on the market in sterile condition

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CLI 061317 0008

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-30

TÜV SÜD Product Service GmbH
Medical and Health Services

Yao He
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Sep 30, 2024 14:21 GMT+2)

Michael Mauermeir
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Rapid SARS-CoV-2 Antigen Test Card	Class D incl. ST/NPT	N/A	Certification as follows: V9 061317 0006 Rev.01 NB# 0123

Legend: ST – self-testing; NPT – near-patient testing; CDx – companion diagnostics

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Not Applicable	N/A	N/A	N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-09-30	713312198; SH2407500_CLI	Initial issue