Notified Body No. 1434	**POLISH CENTRE FOR TESTING AND CERTIFICATION** 469 Puławska Street, 02-844 Warsaw, POLAND **Medical Devices Certification Division** fax 5.1.2e e-mail: - 5.1.2e @pcbc.gov.pl - wyroby.medyczne@pcbc.gov.pl - 5.1.2e @pcbc.gov.pl	(To be filled in by PCBC) Application no.: …… Case no.: …… Date of receipt: …… Date of positive/negative verification of the application: …… Employee of MC/MV Signature of MC/MV Manager ……
APPLICATION FOR CERTIFICATION		**Confidential when completed**

Explanatory notes to the Application Form

The application is not a civil law agreement. It is only the basis for preparing a quotation which will constitute the Annex to the Contract on certification with Notified Body PCBC upon written acceptance by the Applicant.

1. Documents specified in the **List of Documents** (pages 6, 7, 8) shall not be attached to the Application Form but they shall be sent to PCBC within 30 days after signing of the Contract on EC certification.
2. List of codes according to NBOG F 2012-1, NBOG F 2012-2, NBOG F 2012-3 (Jan 2013) (pages 9, 10) does not need to be attached to the Application.
3. Applying for changes in certificate shall cause its withdrawal and issue of a new certificate with updated data.
4. Authorized Representative shall also provide manufacturer's data by completing the top table on page 1.
5. Application form shall be signed by a person whose name is given in KRS (National Court Register) (or certificate of entry in the register of business activity) or by authorized person. It is also recommended to place a personal stamp of the person signing the Application and also the Applicant stamp.
6. Completed and signed Application form shall be sent by fax, e-mail or by post to PCBC address.
7. **Instruction for Use or description of medical device** and **the EC Declaration of Conformity** for the medical device submitted to certification shall be attached to the Application.
8. Documentation of medical device may be provided in Polish or/and English language.
9. OBL (Own Brand Labeller) Manufacturer is an entity introducing, under its own brand, medical devices which have already been subjected to conformity assessment and which bear CE-marking.

1. Applicant identification

☒ Manufacturer ☐ Authorized representative

The full name of Manufacturer: JOYSBIO (Tianjin) Biotechnology Co., Ltd.		
Country: China		
City: Tianjin		Postal code: 300457
Street, number: No.220 Dongting Road		PO box: N/A
E-mail: 5.1.2e @joysbio.com		Website: https://en.joysbio.com/
NIP (taxpayer ID no.) 5.1.2e	REGON (national business registration no.): 5.1.2e	KRS (National Court Register) no.: 5.1.2e
Contact person: 5.1.2e		
Phone: 5.1.2e Fax:		E-mail: 5.1.2e @joysbio.com

To be filled in by the Authorized Representative

The full name of Authorized Representative:		
Country:		
City:		Postal code:
Street, number:		PO box:
E-mail:		Website:
NIP (taxpayer ID no.)	REGON (national business registration no.):	KRS (National Court Register) no.:
Contact person:		
Phone: Fax:		E-mail:

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2. Identification of medical device submitted for certification

Trade name of medical device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
Other names of medical device (*if applicable*):
☐ Type/model/variants of product: in Polish (if applicable):
Number of types/models/variants:
☐ Serial number(s)[1]:
☐ Lot number[1]:

EC assessment: ☒ first, ☐ next for the same device, ☐ change

EC Certificate No.: valid until: [yyyy/mm/dd] Notified Body No.: 1434

Contract No: BR-00/MD-00/RRRR or MD-00/RRRR dated: [yyyy/mm/dd]

☐ **93/42/EEC – MDD – Medical Devices** Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices Rule No.: ____ according to the Regulation of the Minister of Health of 5 November 2010 on methods of medical device classification	☐ Annex II, excluding section 4 ☐ Annex II, section 4 ☐ Annex III ☐ Annex IV ☐ Annex V ☐ Annex VI	☐ Class I[2] ☐ Class I sterile ☐ Class I with a measuring function ☐ Class I with a measuring function, sterile ☐ Sterile systems and procedure packs ☐ Class IIa ☐ Class IIb ☐ Class III
☒ **98/79/EC – IVDD – *In vitro* diagnostic medical devices** Regulation of the Minister of Health of 12 January 2011 on essential requirements and conformity assessment procedures of *in vitro* diagnostic medical devices	☒ Annex III, section 6 ☐ Annex IV, excluding section 4 and 6 ☐ Annex IV, section 4 ☐ Annex IV, section 6 ☐ Annex V ☐ Annex VI ☐ Annex VII	☐ List A ☐ List B ☒ for self-testing
☐ **90/385/EEC – AIMDD – Active implantable medical devices** Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of active implantable medical devices	☐ Annex II, section 4 ☐ Annex II, excluding section 4 ☐ Annex III ☐ Annex IV ☐ Annex V	

[1] Only for Annex IV according to Directive 93/42/EEC, Directive 90/385/EEC and Annex VI according to 98/79/EC.
[2] Without involvement of Notified Body.

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☐ **Change in contents of EC Certificate No.:**	☐ Applicant's address[3]
***)	☐ Applicant's name[3]
information on change in contents of the certificate	☐ Legal status[3]
	☐ Name of medical device[4]
	☐ Extension of the device variant[4]
	☐ Other, what? (include detailed description)

3. Information about the stages of product realization

Stages of product realization	Name and address of the site of product realization stage
Design	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Manufacture5	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Final testing	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Sterilization	
Packaging	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Storage	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Distribution	
Service	JOYSBIO (Tianjin) Biotechnology Co., Ltd, at Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongting Road, TEDA 300457 Tianjin China
Other stages:	

Total number of employees involved in all stages of product realization	Total number of employees 490
Is the Applicant an OBL Manufacturer? ☐ YES ☒ NO	

4. Information on certificate contents

Proposal of EC Certificate content	☐ Polish language ☒ English language
Name of medical device in Polish	
Name of medical device in English	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

5. Information on medical device

☐ disposable product	☐ marketed as a sterile	☐ product contains phthalates
☐ reusable product	☒ marketed as a non-sterile	☐ product contains nanomaterials
☐ possible recycling of the product	☐ product for multiple sterilization	☐ active device for implantation
☐ required supervision of medical waste	☐ steam sterilization	☐ active device
☐ invasive device	☐ ethylene oxide sterilization	☐ non-active device
☒ non-invasive device	☐ sterilization by radiation	☐ device with a measuring function
☐ surgically invasive device	☐ disinfected product	☐ device includes software
☐ implantable device	☐ for temporary use	☐ product utilizing or controlled by computer software
☐ device intended to be fully absorbed	☐ for short-term use	☐ product emits ionizing radiation
☐ product contains biologically active materials covering or being absorbed part or in whole	☐ for long-term use	☐ product emits other radiation than ionizing radiation
☐ *in vitro* diagnostic device	☐ device contains medicinal substances	☐ product to diagnostic radiology

[3] Required KRS copy attached to the Application.
[4] Required explanation attached to the Application.
[5] All production sites (including production of components and special processes) shall be specified.

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☒ *in vitro* for self-diagnosis	☐ device contains stable derivatives of human blood or human plasma (blood product)	☐ product using the micromechanisms
☐ devices containing coating materials	☐ device contains animal tissues	

Description of the device (a brochure and a service manual in Polish or English shall be attached) What is the intended use of the device?	*For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal (NS) swab or saliva specimens directly from individuals who are suspected of COVID-19.*
Was the product placed on the market? How long is the device on the market?	☐ NO ☒ YES ☐ for *1* years
For the device which is marketed, please provide the Notified Body which conducted the conformity assessment procedure	
What is the reason for transfer of product certification to PCBC?	*For certificate of self-testing*
Has an application for certification been submitted to any other Notified Body?	☒ NO ☐ YES Application was submitted to Notified Body No.
If "YES", provide the reasons.	
Has another Notified Body rejected the application for certification of the product concerned?	*No*
If "YES", provide reason for rejection of the application for product certification?	
Have any medical incidents related to the applied product occurred?	*No*

6. Information on the Applicant Quality Assurance System

Is the Quality Assurance System of the Company certified?	☒ YES ☐ NO		
☒ PN-EN ISO 13485 / ENISO 13845	☐ PN-EN ISO 9001 / EN ISO 9001	☐ Good Manufacturing Practice (GMP)	☐ Other
Does the Company work in shift system?	☐ YES ☒ NO If YES, specify the number and hour of shifts:		
Is which language the documentation for assessment in prepared?	☐ Polish ☒ English		

7. Information on product code

Code name *(tick appropriate code with „x")*	Code	Generic name by code *(in English)*
☒ GMDN (AIMDD, MDD)*	64787	64787 SARS-CoV-2 antigen IVD , kit , immunochromatographic test (ICT) , rapid
☐ UMDNS (AIMDD, MDD)		
☐ EDMS (IVDD)		
** GMDN code is preferred*		

8. Information on MD codes of product in comply with the List of MD codes according to NBOG F 2012-1, NBOG F 2012-2, NBOG F 2012-3 (Jan 2013) *(listed on PCBC website)*

Code name	MD Code	Generic name by code
MD (MDS, AIMD, IVD)*		
** Delete unnecessary*		

"The administrator of your personal data is the Polish Center for Testing and Certification S.A. with headquarter in Warsaw (02-844), at ul. Pulawska 469 (hereinafter referred to as PCBC).

For what purpose and on what basis we process your data?
Your personal data will be processed for the conclusion and performance of the contract for the certification of medical devices

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(Article 6 paragraph 1 letter b of the GDPR) and for marketing purposes of PCBC. The legal basis for the processing of your personal data for marketing purposes is art. 6 par. 1 lit. f) GDPR, i.e. the legitimate interest of PCBC which is sending marketing information about PCBC services, including invitations to events and training organized by PCBC. Providing data is not mandatory, but necessary to conclude an agreement between you or the organization you represent and PCBC.
PCBC will transfer your personal data to other recipients entrusted with the processing of personal data on behalf of and for PCBC. Furthermore, PCBC will share your personal data with other recipients, if such obligation will result from legal provisions (including the Polish Center for Accreditation, Registry Office of Medicinal Products, Medical Devices and Biocidal Products, Ministry of Health, European Commission).
Your data will not be transferred to third countries and international organizations.

How long will we process your data?

Your personal data will be processed for the duration of the contract between you and PCBC, as well as for archiving purposes specified in special regulations such as the Accounting Act and the Civil Code. Your personal data for marketing purposes of PCBC will be processed until you submit an objection.

What rights do you have?

You have the right to:
- access to your personal data and receipt of copies of personal data being processed;
- rectification of incorrect data;
- request for deletion of data (the right to be forgotten) in the case of circumstances provided for in art. 17 GDPR;
- requests to limit data processing in cases specified in art. 18 GDPR;
- raising objections to data processing in the cases specified in art. 21 GDPR;
- transfer of supplied data, processed in an automated manner.

If you feel that your personal data is being processed unlawfully, you can file a complaint with the supervisory body (UODO, 2 Stawki Street, Warsaw).

Contact

If you need additional information related to the protection of personal data or want to exercise your rights, contact:
Data Protection Supervisor: 5.1.2e@pcbc.gov.pl

Polish Center for Testing and Certification S.A. with headquarters in Warsaw (02-844), at Puławska str., 469

I declare that the information in the application is correct and true, and that I am aware of the responsibility for making a false declaration.

Place and date of completion of the Application …… Tianjin, China, 2/8/2021

Name of Authorized Person …… 5.1.2e

Authorized Person signature …… 5.1.2e ……

Applicant Company stamp

Does a product fall under the medical device definition? (to be filled in by PCBC's employee)	☐ YES ☐ NO …… Signature of MC Manager/ BM Vice-Director

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Verification of classification/qualification (to be filled in by PCBC's employee)	☐ correct	☐ incorrect Correct according to PCBC …… Signature of MC Manager/ BM Vice-Director