Application for assessing the self-testing IVD tests

From: 5.1.2e <5.1.2e@atlas-link.com>
Sent: Monday, March 1, 2021 6:14 AM
To: 5.1.2e <5.1.2e@pcbc.gov.pl>
Subject: NB / Certification of COVID-19 Related Products

Dear 5.1.2e,

Thanks your reply to my email.

Actually I have almost finished filling the application form. But before sending, I have to state the current status of our products and want to get the confirmation by your side.

Our COVID-19 Antigen Rapid Test belongs to low risk class, so there is no need to pass its assessment to the NB before (also our products have been placed on the market). We submit this application, aiming for further assessment by you as the SELF-TESTING ones.

I wonder whether your company could accept the application for assessing the self-testing IVD tests?

Looking forward to your reply.

Yours Sincerely,

5.1.2e

Cell: +5.1.2e
Email: 5.1.2e@atlas-link.com

From: 5.1.2e <5.1.2e@pcbc.gov.pl>
Sent: Monday, March 1, 2021 17:38
To: 5.1.2e <5.1.2e@atlas-link.com>
Subject: NB / Certification of COVID-19 Related Products

Dear 5.1.2e,
Thank you for your message.
We accept application for the self-test IVD test, including Covid-19 antigen tests.

Kind regards,

5.1.2e
5.1.2e

Medical Devices Certification Department

Mobile: + 5.1.2e
E-mail: 5.1.2e @pcbc.gov.pl

From: 5.1.2e <5.1.2e @atlas-link.com>
Sent: Tuesday, March 2, 2021 3:40 AM
To: 5.1.2e <5.1.2e @pcbc.gov.pl>
Subject: NB / Certification of COVID-19 Related Products

Dear 5.1.2e

That's really a good news! Thanks for your information!

The finished form is in the attachment, but, there are still some blanks I cannot fill in, such as Part 7. Also in regard to what I have described in the form, is there any question on the products or qualifications from your side?

After confirming all information in the form by our two sides, the form will be signed and sent to you ASAP.

Thanks and Regards,

5.1.2e

Cell: + 5.1.2e
Email: 5.1.2e @atlas-link.com

From: 5.1.2e <5.1.2e @pcbc.gov.pl>
Sent: Tuesday, March 2, 2021 15:19
To: 5.1.2e <5.1.2e @atlas-link.com>
Subject: RE: NB / Certification of COVID-19 Related Products

Dear 5.1.2e ,
Thank you for the application form.
In section 7 you should put a code from one of the databases that you have access to.
I also need an IFU/brochure of the product.

Looking forward to hearing from you.

Best regards,
5.1.2e

5.1.2e
Medical Devices Certification Department

Mobile: + 5.1.2e
E-mail: 5.1.2e

Notified Body No. 1434	**POLISH CENTRE FOR TESTING AND CERTIFICATION** 469 Puławska Street, 02-844 Warsaw, POLAND **Medical Devices Certification Division** fax +48 22 46 45 251 e-mail: - 5.1.2e @pcbc.gov.pl - 5.1.2e @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: Atlas Link Technology Co., Ltd.		
Country: the People's Republic of China		
City: Langfang City, Hebei Province	Postal code: 065500	
Street, number: Gu'an South Industry Zone	PO box: N/A	
E-mail: 5.1.2e @atlas-link.com	Website: http://www.atlas-link.com/english/	
NIP (taxpayer ID no.): 911310225619870608	REGON (national business registration no.): (China -- 911310225619870608)	KRS (National Court Register) no.: N/A
Contact person: 5.1.2e		
Phone: 5.1.2e	Fax: 5.1.2e	E-mail: 5.1.2e @atlas-link.com

To be filled in by the Authorized Representative

The full name of Authorized Representative: MT Promedt Consulting GmbH		
Country: Germany		
City: St. Ingbert	Postal code: 66386	
Street, number: Altenhofstrasse 80	PO box: N/A	
E-mail: 5.1.2e @mt-procons.com	Website: None	
NIP (taxpayer ID no.)	REGON (national business registration no.):	KRS (National Court Register) no.:
Contact person: 5.1.2e		

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Phone: + 5.1.2e Fax: None E-mail: 5.1.2e @mt-procons.com

2. Identification of medical device submitted for certification

Trade name of medical device: NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)
Other names of medical device (*if applicable*): N/A
☐ Type/model/variants of product: in Polish *(if applicable)*: N/A
Number of types/models/variants: N/A
☐ Serial number(s)[1]:
☒ Lot number[1]: nCOV-500

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	☐ 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
Rule No.: according to the Regulation of the Minister of Health of 5 November 2010 on methods of medical device classification		
☒ **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	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Manufacture5	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Final testing	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Sterilization	N/A, Sampling swab is sterilized by it manufacture.
Packaging	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Storage	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Distribution	Atlas Link Technology Co., Ltd ☐Address: Gu'an South Industry Zone, 065500 Langfang City, Hebei Province, the People's Republic of China
Service	
Other stages:	

Total number of employees involved in all stages of product realization:	Total number of employees:
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	NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

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

[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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☐ 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
☒ *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?	*NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is a lateral flow immunoassay for the detection of novel coronavirus (SARS-CoV-2) antigens in pharyngeal and nasal swab samples.* *The product is designed to be used for population screening early phase for disease outbreaks. Testing is limited to laboratories certified. Results are for the identification of SARS-CoV-2 nucleocapsid antigen.* *This antigen is generally detectable in upper respiratory samples during the acute phase of infection. For professional use only.*
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	*Because our Antigen Rapid Test Kit belongs to low risk class, so there is no need to pass its assessment to the NB before (also our products have been placed on the market, as described in Part 3). We submit this application for further assessment as the SELF-TESTING ones.*
What is the reason for transfer of product certification to PCBC?	We want our Antigen Rapid Test Kit can be certified according to the requirements 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.	1. TÜV Rheinland (Great China) The reason is that they have not yet started accepting CE approval application for COVID-19 self-testing devices. 2. TÜV SÜD (Great China) The reason is based on the product risk of self-testing products abut SARS-CoV-2
Has another Notified Body rejected the application for certification of the product concerned?	TÜV SÜD (Great China)
If "YES", provide reason for rejection of the application for product certification?	Base on the product risk of self-testing products about SARS-COV-2
Have any medical incidents related to the applied product occurred?	None

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)*		
☐ UMDNS (AIMDD, MDD)		
☒ EDMS (IVDD)	15 70 90 90 00	OTHER OTHER VIROLOGY RAPID TESTS

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* *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)*	IVD 0403	Immunology

* *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. Puławska 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 (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 …Beijing, P.R. China, Mar 08, 2021 Manager Director

Name of Authorized Person 5.1.2e

Authorized Person signature 5.1.2e

5.1.2e

licant Company stamp

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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
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