Polish Centre for Testing and Certification.
Notified Body No. 1434
469 Puławska Street, 02-844 Warsaw
www.pcbc.gov.pl
Medical Devices Certification Division

OFFER of 18.02.2021

This offer is valid for 30 days from the date of issue.

Contract for certification shall be concluded within the validity of the offer.

Application no. 034/2021

Name of medical device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Type: SARS-CoV-2 Antigen Rapid Test Kit (Saliva), SARS-CoV-2 Antigen Rapid Test Kit (Nasal Swab)

EC Directive: 98/79/EC

Annex to the EC Directive: Annex III, section 6

Classification/Qualification of medical device: for self-testing

Manufacturer's name and address: JOYSBIO (Tianjin) Biotechnology Co., Ltd. No.220 Dongting Road, 300457 Tianjin

Type of service	Net price USD
Initial fee	2439,00
Assessment of documentation in PCBC*	74325,00

Type of service	Number of days	Net price USD
Certification audit	-	-

IN TOTAL (initial fee, assessment of documentation, certification audit)	**76764,00**

Type of service	Number of days	Net price USD
Annual analysis of documentation to maintain the validity of certificates - carried out for product recertification in 2024.	-	26014,00

An unannounced audit – one permissible during certification period.

Type of service	Number of days	Net price USD
An unannounced audit	-	-

***The certificate is issued for one year and maintenance of its validity requires the annual re-evaluation in the amount of 35% of the certification costs for each subsequent year – according to the table above.**

Special audit - the cost of the audit under which it is performed (certification/ surveillance/ unannounced audit).

Additional information

All above prices do not include VAT, travel and accommodation costs.

Fee for the opinion of the President of the URPL (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) / EMA (the European Medicines Agency) shall be borne by the Customer.

Issue of the duplicate certificate: 55 USD

Legalization/apostille of the certificate: 280 USD

Verification of the lot (IVD list A): 420 USD*

Analysis and assessment of documentation due to changes: 420- 1415 USD

Participation of the expert in assessment of documentation due to changes: 420 - 1270 USD

*Excluding the costs of BV studies performed at external laboratory

Adam Sobantka/Monika Mroczkiewicz

Elektronicznie podpisany przez Monika Elżbieta Mroczkiewicz

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Director/Vice-Director of Medical Devices Certification Division

Client approval:

Wukui Huo

Digitally signed by Wukui Huo
Date: 2021.02.19 04:05:42 -08'00'

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Name and surname of authorized person