No. Siri:
Serial No.: **051754**

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **IVDC9540322-106750**
Registration No.:

Tarikh Sah Pendaftaran: **25/10/2022 - 24/10/2027**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **MEDICAL INNOVATION VENTURES SDN BHD**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

1ST FLOOR OF PLOT 88F, LINTANG BAYAN LEPAS 10, BAYAN LEPAS INDUSTRIAL PARK, PHASE 4, ,
11900
BAYAN LEPAS PULAU PINANG PULAU MUTIARA

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **IVDC9540322-106750**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**SARS-COV-2 ANTIGEN RAPID TEST CASSETTE**		
Kelas *Class*	**CLASS C**	Jenama *Brand*	**SEJOY**
Kelompok *Group*	**IVD TEST KIT**		
Displin *Discipline*	**Immunochemistry**	Kategori *Category*	**Viral Infection - Immunology**
Nama dan alamat pembuat: *Name and address of manufacturer*	**HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD. AREA C, BUILDING 2, NO.365, WUZHOU ROAD, YUHANG ECONOMIC DEVELOPMENT ZONE, 311100 HANGZHOU CITY,ZHEJIANG, CHINA, 311100 CHINA**		

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	SARS-CoV-2 Antigen Rapid Test Cassette	COVG-602ST	SARS-CoV-2 Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in human saliva.
"End Of Product List"			

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
ARAS 6, PRIMA 9, PRIMA AVENUE II, BLOCK 3547
PERSIARAN APEC, 63000 CYBERJAYA.
TEL : (+603)8230 0300

Medical Device AUTHORITY MALAYSIA

Ref : MDR-20231211-86630
Date : 26-01-2024

To whom it may concern,

Dear Sir/Madam,

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (CATEGORY 2)

The above matter is referred.

Please be informed that your change notification request for the medical device as follows has been approved.

Establishment Name	: **MEDICAL INNOVATION VENTURES SDN BHD**
Medical Device Registration Certificate No.	: IVDC9540322-106750
Medical Device Name	: SARS-COV-2 ANTIGEN RAPID TEST CASSETTE
Description of Change	: **Refer Attachment of Approval**

2. This change notification shall be attached together with the medical device registration certificate. The validity of this document shall follow the date as stated in the medical device registration certificate.

Thank you,

MURALITHARAN PARAMASUA
CHIEF EXECUTIVE
Medical Device Authority,
Ministry of Health Malaysia.

Ref : MDR-20231211-86630
Date : 26-01-2024

Attachment of Approval

Change Notification for Category 2

TYPE OF CHANGE(S)	DESCRIPTION OF CHANGE(S)
5.5.2 Changes in design or specifications of a registered medical device	
(c) All changes in specifications (including shelf life and stability) of a registered medical device.	Information has been updated in technical documents

The stability statement

The stability of our COVG-602ST SARS-CoV-2 Antigen Rapid Test Cassette (Saliva) produced by Hangzhou Sejoy Electronics was verified in the early stage, but the follow-up test was not carried out when the storage expiry date was guaranteed to meet 24 months, and the expiry date was tentatively valid for 24 months. However, we re-verified the stability in the later period, and the test data was sufficient to support our products to meet the storage expiry date of 36 months. We hereby declare that.

The detailed information of the supplementary verification experiment is in Annex 1.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

2023-11-25

Annex 1

Accelerated Stability Study Report

Operator: **Hao Wu** **Position:** **Research and development engineer**

Reviewer: **Gang Qian** **Position:** **Project Manager**

Experiment date: **2023.10.8 - 2023.11.25**

- Reference standard

CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents

ISO 23640 - Evaluation of stability of in vitro diagnostic reagents for guidance

- Purpose of verification

Accelerated stability is to investigate whether the technical indicators of the reagent are still within an acceptable and reasonable range in a specific extreme environment, so as to evaluate the performance of the reagent.

- The principle of 55℃ Celsius aging test

Arrhenius equation; Created by Arrhenius of Sweden, it is an empirical formula expressing the dependence of the chemical reaction rate constant (k) on the temperature (T). The formula is as follows: $d(\ln k)/dT=Ea/RT^2$ (Ea is the apparent activation energy, and R is the molar gas constant. The trend of change is that T increases, and generally k also increases.) So 55℃ 16 days equals 1 year at room temperature,31 days equals 2 years at room temperature， 45 days equals 3 years at room temperature.

- Verification plan

The COVG-602ST SARS-CoV-2 Antigen Rapid Test Cassette (Saliva) were placed at 55 ℃ ,respectively to verify the accelerated stability of the product after being stored at room temperature 2-30℃ for 1 year The test products were tested with company internal negative reference panel,L (low value positive reference panel),H (high value positive reference panel). The testing is carried out at the following time points. The accelerated test at 55°C lasts for 46 days.Each sample is tested 5 times and the results are recorded at 20 minutes.

Date (day) / Temperature	0	7	9	14	16	24	28	31	35	39	43	46
55℃	√	√	√	√	√	√	√	√	√	√	√	√

- Acceptance Criteria

The result is G6-G8.5 when the high-value enterprise reference panel H is measured; the result is G3-G4.5 when the low-value enterprise reference panel L is measured; the result is negative when the negative enterprise reference panel is measured.

- Product information

Product name	LOT	Date of production	Storage expiry date
SARS-CoV-2 Antigen Rapid Test Cassette (Saliva)	COVG210806	2022-02	2023-08

- Instruments used for studies

Instrument name	Instrument code:
55℃ oven	SSC-034-02

- Results

55℃

Day	T/H	Enterprise reference panel	Lot				
			COVG210806				
0 (23/10/8)	24.2℃/ 44%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
7 (23/10/15)	25.7℃/ 43%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
9 (23/10/17)	26.3℃/ 47%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
14 (23/10/22	26.5℃/ 40%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
17 (23/10/25)	25.5℃/ 42%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
24 (23/11/4)	25.5℃/ 46%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
28 (23/11/8)	25.8℃/ 43%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
31 (23/11/11)	26.1℃/ 49%	N	G1	G1	G1	G1	G1
		L	G4	G3.5	G4	G4	G4
		H	G8	G8	G7.5	G8	G8
35 (23/11/15)	27.1℃/ 45%	N	G1	G1	G1	G1	G1
		L	G3.5	G4	G4	G4	G3.5
		H	G8	G7.5	G8	G8	G8
39 (23/11/8)	26.8℃/ 41%	N	G1	G1	G1	G1	G1
		L	G4	G4	G4	G4	G4
		H	G8	G8	G8	G8	G8
43 (23/11/11)	26.1℃/ 49%	N	G1	G1	G1	G1	G1
		L	G4	G3.5	G4	G4	G4
		H	G8	G8	G7.5	G8	G8
46 (23/11/15)	26.1℃/ 45%	N	G1	G1	G1	G1	G1
		L	G3.5	G4	G4	G4	G3.5
		H	G8	G7.5	G8	G8	G8

- Summary and discussion of results

The above data shows that the results meet the acceptance criteria. The test at 55℃ for more than 45 days meets the acceptance standard.

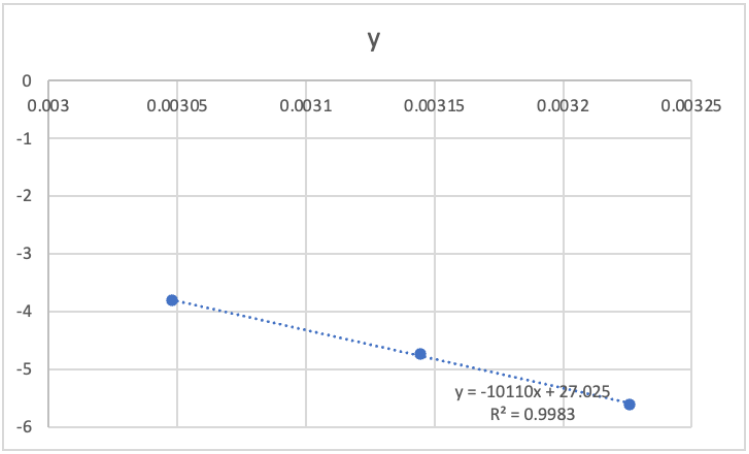
- Estimated expiry date

Environment (℃)	Estimated expiry date (day)
55	45

Arrhenius equation：$K=Ae^{-E/RT}$

A： Pre-exponential factor (also known as frequency factor)；
K： chemical reaction rate constant；
R： molar gas constant；
T： thermodynamic temperature；
E： apparent activation energy；
e： Natural logarithmic base.

Temperature (℃)	Thermodynamic temperature (T)	X（1/T）	Expiry date (d)	1/d	Y [ln(1/d)]
55	328	0.003049	45	0.022222222	-3.8066625898



Regression statistics：n=3，y =-10110x + 27.025，a=-10110，b=27.025，$R^2 = 0.9983$

By regression calculation, at the thermodynamic temperature of 297K at 24℃, expected stable days of [ln (1/d)] :1/297 is -7.0154039697， the number of objections is 0.00089794, the inverse is 1113.66 days, approximately 37.12 months.

- Conclusion

The SARS-CoV-2 Antigen Rapid Test Cassette (Saliva) meet requirements at 55℃ for more than 45 days; The data is plotted on the Arrhenius chart, and the expected shelf life of the product is determined to be at least 36 months from the date of manufacture. The formula is as follows: $d(\ln k)/dT=Ea/RT^2$ (Ea is the apparent activation energy, and R is the molar gas constant. The trend of change is that T increases, and generally k also increases.) . Based on the accelerated stability test data and the Arrhenius equation, the storage expiry date of SARS-COV-2 Antigen Rapid Test Cassette (Saliva) produced by Hangzhou Sejoy Electronics & Instruments Co.,Ltd. at 24℃ was 37.12 months.

SEJOY

Sejoy Biomedical Co., Ltd.

Add:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang P.R. China

URGENT - Field Safety Notice

To all users of the SARS-COV-2 ANTIGEN RAPID TEST CASSETTE (SEJOY)

Re: SARS-COV-2 ANTIGEN RAPID TEST CASSETTE (SEJOY)- EXTENSION SHELF LIFE.

Dear customers,

This letter is to inform you that our authorized representative Medical Innovation Ventures Sdn. Bhd. (MEDIVEN) had obtained the approval for the extension of the shelf-life for SARS-COV-2 ANTIGEN RAPID TEST CASSETTE as per the details below:

Brand:	SEJOY
Reference No:	COVG-602ST
Lot No:	COVG210806
Extended Shelf-life:	24 MONTHS

When was the approval obtained and what are the potential risks?
The Change Notification approval letter from Medical Device Authority (MDA) was received by MEDIVEN on 11/04/2023 for the extension shelf-life.
The use of unverified shelf-life COVID-19 self-test kits may cause inaccurate results for users.

What steps can the user take to avoid the potential risk of this issue?
To minimize the potential risk, our authorized representative, MEDIVEN has taken the following steps:

i) With immediate effect, placed the extension of shelf-life sticker on the box of the product.
ii) With immediate effect, posted the approval from MDA regarding the extension of shelf-life for SEJOY on our website with immediate effect.
iii) With immediate effect, sent the approval letter to notify all distributors on the extension of shelf-life.
iv) MEDIVEN wrote to the Ministry of Health Malaysia (MoH) on 4/1/2024 to place a notification on MoH's social media platform to inform the public about the MDA-approved extended shelf-life of COVID-19 rapid self-test kits.
v) MoH acknowledged the receipt of MEDIVEN's request by issuing notification on their social media on 6/1/2024 (https://m.facebook.com/story.php?story_fbid=pfbid02BMcQGqM5he65QwAJHcp9ZGWaSp79BuKRvcLn7bSH8AAaWHC1DH5EnFgBCqvnZUukl&id=100064560379224&mibextid=Nif5oz)

To minimize the potential risk, the user is required to take the following steps:

i) Check for MDA-approved shelf-life extension on the labelling before purchase.
ii) Contact the distributor/manufacturer of the COVID-19 rapid self-test kits to verify the approval.

Sejoy Biomedical Co., Ltd.

Add:Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City, 311100 Zhejiang P.R. China

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Name
Position Sales Director

浙江世佳生物医疗有限公司
SEJOY BIOMEDICAL CO.,LTD.

Contact person of this notification:

Department: Regulatory Affairs
Telephone : +604 305 2730
Fax : +604 3052730
E-mail : regulatory@mediven.com.co

URGENT - Field Safety Notice

To all users of the SARS-COV-2 ANTIGEN RAPID TEST CASSETTE (SEJOY)

Re: SARS-COV-2 ANTIGEN RAPID TEST CASSETTE (SEJOY)- EXTENSION SHELF LIFE.

Dear customers,

This letter is to inform you that Medical Innovation Ventures Sdn. Bhd. (MEDIVEN) had obtained the approval for the extension of the shelf-life for SARS-COV-2 ANTIGEN RAPID TEST CASSETTE as per the details below:

Brand: SEJOY
Reference No: COVG-602ST
Lot No: COVG210806
Extended Shelf-life: 24 MONTHS

When was the approval obtained and what are the potential risks?
The Change Notification approval letter from Medical Device Authority (MDA) was received by MEDIVEN on 11/04/2023 for the extension shelf-life.
The use of unverified shelf-life COVID-19 self-test kits may cause inaccurate results for users.

What steps can the user take to avoid the potential risk of this issue?
To minimize the potential risk, MEDIVEN has taken the following steps:

i) With immediate effect, placed the extension of shelf-life sticker on the box of the product.
ii) With immediate effect, posted the approval from MDA regarding the extension of shelf-life for SEJOY on our website with immediate effect.
iii) With immediate effect, sent the approval letter to notify all distributors on the extension of shelf-life.
iv) MEDIVEN wrote to the Ministry of Health Malaysia (MoH) on 4/1/2024 to place a notification on MoH's social media platform to inform the public about the MDA-approved extended shelf-life of COVID-19 rapid self-test kits.
v) MoH acknowledged the receipt of MEDIVEN's request by issuing notification on their social media on 6/1/2024 (https://m.facebook.com/story.php?story_fbid=pfbid02BMcQGqM5he65QwAJHcp9ZGWaSp79BuKRvcLn7bSH8AAaWHC1DH5EnFgBCqvnZUukl&id=100064560379224&mibextid=Nif5oz)

To minimize the potential risk, the user is required to take the following steps:

i) Check for MDA-approved shelf-life extension on the labelling before purchase.
ii) Contact the distributor/manufacturer of the COVID-19 rapid self-test kits to verify the approval.

Medical Innovation Ventures Sdn. Bhd (Mediven)
1st Floor of Plot 88F,Lintang Bayan Lepas 10,
Bayan Lepas Industrial Park, Phase 4,
11900 Bayan Lepas, Penang.
Office: +604 305 2730 Fax: +604 3052730
Email: admin@mediven.com.co

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

_____

Lim Li Sze
Operation Directors
24/01/2024

Contact person of this notification:

Department: Regulatory Affairs
Telephone : +604 305 2730
Fax : +604 3052730
E-mail : regulatory@mediven.com.co