No. Siri:
Serial No.: **051795**

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: **IVDB7832122-106859**
Registration No.:

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

Sijil ini adalah dengan ini diberi kepada: **EMERGO MALAYSIA SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

LEVEL 16, 1 SENTRAL, JALAN STESEN
SENTRAL 5, KL SENTRAL,
50470
KUALA LUMPUR

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: **IVDB7832122-106859**
Registration No.:

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

Nama Peranti Perubatan *Medical Device Name*	**NUCLEIC ACID EXTRACTION RAPID KIT (MAGNETIC BEAD METHOD)**
Kelas *Class*	**CLASS B**
Jenama *Brand*	**BIOPERFECTUS TECHNOLOGIES**
Kelompok *Group*	**IVD TEST KIT**
Displin *Discipline*	**Immunochemistry**
Kategori *Category*	**Viral Infection – Immunology**
Nama dan alamat pembuat: *Name and address of manufacturer*	**JIANGSU BIOPERFECTUS TECHNOLOGIES CO., LTD. 3RD AND 4TH FLOORS OF BUILDING A(G19), 4TH FLOOR OF BUILDING F(G14), GROUND FLOOR OF BUILDING G20, SHUAIYU VILLAGE, FUYE VILLAGE, SIXIANG TOWN, TAIZHOU NATIONAL MEDICAL, HI-TECH DEVELOPMENT ZONE, 225300 TAIZHOU, JIANGSU, PEOPLE'S REPUBLIC OF CHINA. , 225300 CHINA**

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Nucleic Acid Extraction Rapid Kit (Magnetic Bead Method)	SDKF60101	This kit uses magnetic beads and buffer system with unique separation function and is used in conjunction with nucleic acid extractor to separate and purify high-quality viral nucleic acids from samples. The specially coated magnetic beads have a strong affinity for the nucleic acid in the sample under certain conditions. When the conditions change, the magnetic beads release the adsorbed nucleic acid, so that the nucleic acid in the purified sample can be quickly extracted. The kit is available in 32T/ 48T/ 96T. Kit components include: Lysis binding solution, washing liquid, Magnetic bead solution, Eluent, Magnetic rod stirring sleeve.
"End Of Product List"			

No. Siri:
Serial No.: 044654

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: **IVDA2943021-82118**
Registration No.:

Tarikh Sah Laku Pendaftaran: **29/12/2021 -**
Registration Validity Date: **28/12/2026**

Sijil ini adalah dengan ini diberi kepada: **EMERGO MALAYSIA SND. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

LEVEL 16, 1 SENTRAL, JALAN STESEN SENTRAL
5, KL SENTRAL,
50470
KUALA LUMPUR

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: **IVDA2943021-82118**
Registration No.:

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

Nama Peranti Perubatan **Nucleic Acid Extraction System**
Medical Device Name

Kelas **CLASS A** Jenama **Nucleic Acid Extraction System**
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **JIANGSU BIOPERFECTUS TECHNOLOGIES CO., LTD. 3RD AND 4TH FLOORS OF BUILDING A(G19), 4TH FLOOR OF BUILDING F(G14), GROUND FLOOR OF BUILDING G20, SHUAIYU VILLAGE, FUYE VILLAGE, SIXIANG TOWN, TAIZHOU NATIONAL MEDICAL, HI-TECH DEVELOPMENT ZONE, 225300, CHINA**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Nucleic Acid Extraction System	SSNP-2000B	This product is used in the virus nucleic acid extraction kit (magnetic beads method) for nucleic acid extraction. Software Version is V1.0
2	Nucleic Acid Extraction System	SSNP-3000A	This product is used in the virus nucleic acid extraction kit (magnetic beads method) for nucleic acid extraction. Software Version is V1.0
3	Nucleic Acid Extraction System	SSNP-9600A	This product is used in the virus nucleic acid extraction kit (magnetic beads method) for nucleic acid extraction. Software Version is V1.0
4	Nucleic Acid Extraction System	SMPE-960	This product is intended for use with magnetic bead-based nucleic acid extraction kits for the extraction and purification of nucleic acids from clinical samples. Software Version is V1.0
"End Of Product List"			