



SINGAPORE ACADEMY OF LAW

AUTHENTICATION CERTIFICATE

I hereby certify that –

Lim Biow Chuan is a duly appointed Notary Public practising in Singapore, and that the signature appearing at the foot of the annexed Notarial Certificate dated 8th June 2017, is the signature of the said Lim Biow Chuan.

This Certificate is not valid if the seal of the Singapore Academy of Law is removed or altered in any way whatsoever. This Certificate does not authenticate or confirm the content of the Document attached to the annexed Notarial Certificate.

Dated this 8th day of June 2017.

LOW HUI MIN
DIRECTOR
SINGAPORE ACADEMY OF LAW

Certified true signature

17060936

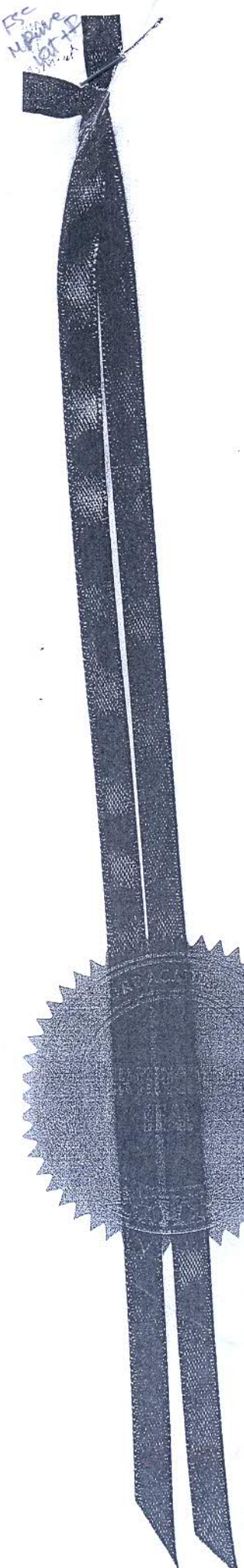


EJILANE

09 JUN 2017

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ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO
Embassy of the S.R. of Vietnam in the Republic of Singapore

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia / Country: **Xinh-ga-po / Singapore**
Giấy tờ, tài liệu này / This public document

2. do Ông (Bà) / has been signed by: **EJILANE**
3. với chức danh / acting in the capacity of: **VIÊN CHỨC LÃNH SỰ**

4. và con dấu của / bears the seal/stamp of: **BỘ NGOẠI GIAO XHCN VIỆT NAM**
được chứng nhận / hợp pháp hóa lãnh sự / Certified

5. Tại / at: **XINH-GA-PO / Singapore** 6. ngày / date: **09/06/2017**

7. Cơ quan cấp / by: **ĐSQ nước CHXHCN Việt Nam tại CH Xinh-ga-po**
8. Số / N°: **53**
Embassy of the S.R. of Vietnam in the Republic of Singapore

Ký tên và đóng dấu / Signature and seal/stamp

Tham tá / Counsellor



Nguyễn Thị Thanh Xuân

CHỨNG THỰC BẢN SAO ĐÚNG VỚI BẢN CHÍNH

Số chứng thực: **055412** Quyền số: **07** năm **2017** 'BS

Ngày **12** tháng **07** năm **2017**

PHÓ TRƯỞNG PHÒNG TƯ PHÁP QUẢN LÝ



Nguyễn Võ Uyên Linh

NOTARIAL CERTIFICATE

TO ALL TO WHOM THESE PRESENTS SHALL COME

I, **LIM BIOW CHUAN**, Notary Public, duly authorized and appointed, practising in the Republic of Singapore **DO HEREBY CERTIFY AND ATTEST**, that the attached **Certified True Copy of Certificate Of Free Sale For Medical Device** (Certificate No. FSC/167/2017) with attachments issued by the **Health Sciences Authority Republic of Singapore** on 02 Jun 2017 was signed and certified by Mr Adrian de Jong on the said document as a true copy of the original document.

IN TESTIMONY WHEREOF I have hereunto subscribed my NAME and affixed my SEAL OF OFFICE this 8th day of June 2017.



**LIM BIOW CHUAN
NOTARY PUBLIC
SINGAPORE**





ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO
Embassy of the S.R. of Vietnam in the Republic of Singapore

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia **Xinh-ga-po**
Country Singapore
Giấy tờ, tài liệu này
This public document
2. do Ông (Bà) **LIM BIOW CHUAN** ký
has been signed by
3. với chức danh **Công chứng viên**
acting in the capacity of
4. và con dấu của **Sở Công chứng Xinh-ga-po**
bears the seal/stamp of
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. Tại **XINH-GA-PO** 6. ngày
at Singapore date 09/06/2017
7. Cơ quan cấp ĐSQ nước CHXHCN Việt Nam tại CH Xinh-ga-po
by Embassy of the S.R. of Vietnam in the Republic of Singapore
8. Số N° 53

Ký tên và đóng dấu
Signature and seal/stamp

Tham tán/ Counsellor





Health Sciences Authority
Republic of Singapore

HSA 600:36/18
Date of Issue: 02 Jun 2017

Certificate No.
FSC/167/2017

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICE

It is hereby certified that the following medical device products may be supplied in Singapore. Pursuant to regulation 10B of the Health Products (Medical Devices) Regulations, and subject to its requirements, the following Class A medical device product is not required to be registered before sale.

- Device Proprietary/Brand Name* : *Please refer to attached Schedule.*
- Intended Use* : *Please refer to attached Schedule.*
- Manufacturing Site* : *MP BIOMEDICALS ASIA PACIFIC PTE LTD
2 PIONEER PLACE SINGAPORE 627885*
- Product Owner* : *MP BIOMEDICALS ASIA PACIFIC PTE LTD
2 PIONEER PLACE SINGAPORE 627885*
- Applicant* : *MP BIOMEDICALS ASIA PACIFIC PTE LTD
2 PIONEER PLACE SINGAPORE 627885*

NOTARY ATTESTATION



Please refer overleaf for a definition of the terms used in this certificate.

- 2 This Certificate expires 24 months from the date of issuance.
- 3. The information provided and attached Schedule is correct on the date of issuance.

LAKSHMIDEVI BALAKRISHNAN
SENIOR REGULATORY SPECIALIST
for GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY



Certified True Copy

ADRIAN DE JONG
SENIOR MANAGER QARA
MP BIOMEDICALS ASIA PACIFIC PTE LTD
2 Pioneer Place Singapore 627885
Tel: (65) 6775-0008 Fax: (65)
Co. Regn. No.: 198403141W

This certificate shall not be construed as an endorsement of the medical device product by the Health Sciences Authority.....

Definition of Terms

Manufacturing Site:

The location where the manufacture/site of a health product is carried out.

Manufacture, in relation to a health product, means to make, fabricate, produce or process the health product and includes —

- (a) any process carried out in the course of so making, fabricating, producing or processing the health product; and
- (b) the packaging and labelling of the health product before it is supplied;

Product Owner:

in relation to a health product, means a person who —

- (a) supplies the health product under his own name, or under any trade-mark, design, trade name or other name or mark owned or controlled by him; and
- (b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf



Registrant:

in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the Health Products Act

Supply

in relation to a health product, means to transfer possession of the health product by any means whether or not for reward, and includes the following:

- (a) to sell the health product, whether by retail, wholesale or auction;
- (b) to expose or display the health product as an invitation to treat;
- (c) to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;
- (d) to supply the health product in connection with —
 - (i) a contract for the provision of any goods or the performance of any service; or
 - (ii) any advertising, sponsorship or promotional activity;
- (e) to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;
- (f) to offer, agree or attempt to supply the health product in any of the ways described in paragraphs (a) to (e) or to cause or permit the health product to be so supplied;
- (g) to keep or possess the health product in any of the ways described in paragraphs (a) to (f).

	
ĐẠI SỨ QUÁN NƯỚC CỘNG HÒA XHCN VIỆT NAM TẠI CH XINH-GA-PO <i>Embassy of the S.R. of Vietnam in the Republic of Singapore</i>	
CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ <i>CONSULAR AUTHENTICATION</i>	
1. Quốc gia <i>Country</i>	Xinh-ga-po <i>Singapore</i>
Giấy tờ, tài liệu này <i>This public document</i>	
2. do Ông (Bà) <i>has been signed by</i>	LIM BIOW CHUAN
3. với chức danh <i>acting in the capacity of</i>	Công chứng viên
4. và con dấu của <i>bears the seal/stamp of</i>	Sở Công chứng Xinh-ga-po <i>được chứng nhận / hợp pháp hóa lãnh sự</i> <i>Certified</i>
5. Tại <i>at</i>	XINH-GA-PO <i>Singapore</i>
6. ngày <i>date</i>	09/06/2017
7. Cơ quan cấp <i>by</i>	ĐSQ nước CHXHCN Việt Nam tại CH Xinh-ga-po. <i>Embassy of the S.R. of Vietnam in the Republic of Singapore</i>
8. Số <i>Nº</i>	53
Ký tên và đóng dấu <i>Signature and seal/stamp</i>	
Tham tán/Counselor <i>Nguyen Thi Thanh Xuan</i>	
	

THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use (Not More than 200 words)	Device Class and the applicable Risk Classification Rule*
1	MP Diagnostics MPure Blood DNA Extraction Kit 200	The MP Diagnostics MPure Blood DNA Extraction Kit 200 is used with the MPure-12 aNAP System for extraction of DNA from 10 - 400µl mammalian whole blood, suspension of mammalian blood cells.	Class A IVD, Rule 5
2	MP Diagnostics MPure Blood DNA Extraction Kit 1200	The MP Diagnostics MPure Blood DNA Extraction Kit 1200 is used with the MPure-12 aNAP System for extraction of genomic DNA from 400-1000µl mammalian whole blood, suspension of mammalian blood cells.	Class A IVD, Rule 5
3	MP Diagnostics MPure Viral Nucleic Acid Extraction Kit	The MP Diagnostics MPure Viral Nucleic Acid Extraction Kit is used with the MPure-12 aNAP System for extraction of viral DNA or RNA from human biological specimens such as serum, plasma, and other cell-free fluids.	Class A IVD, Rule 5
4	MP Diagnostics MPure Tissue DNA Extraction Kit	The MP Diagnostics MPure Tissue DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA from a variety of animal tissues, swab samples and blood stain.	Class A IVD, Rule 5
5	MP Diagnostics MPure Cultured Cell DNA Extraction Kit	The MP Diagnostics MPure Cultured Cell DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA from genomic DNA from culture cells and buffy coat.	Class A IVD, Rule 5
6	MP Diagnostics MPure Bacterial DNA Extraction Kit	The MP Diagnostics MPure Bacterial DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA from both Gram-positive and Gram-negative bacteria.	Class A IVD, Rule 5

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THE SCHEDULE

7	MP Diagnostics MPure HPV DNA Extraction Kit for Swab Sample	<p>The MP Diagnostics MPure HPV DNA Extraction Kit for Swab Sample is used with the MPure-12 aNAP System for DNA extraction of the Human Papillomavirus (HPV) from cervical cell samples which collected by cervical brush or genital swab in liquid-based Medium* (e.g. Hologic Thinprep PreservCyt®, BD Surepath™, etc.) or other STM (sample transport media) preservation solutions (e.g. QIAGEN DNA PAP Cervical sampler, Roche Cobas® PCR Cell Collection Media, HybriBio cell preservation solution, etc.).</p> <p>*The liquid-base medium are formulated for cellular preservation and used in liquid-based cytological systems (LBC) for cytological and molecular diagnosis.</p>	Class A IVD, Rule 5
8	MP Diagnostics MPure TB DNA Extraction Kit	The MP Diagnostics MPure TB DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA of <i>Mycobacteria</i> spp. (e.g. <i>Mycobacterium tuberculosis</i>) from different specimens.	Class A IVD, Rule 5
9	MP Diagnostics MPure FFPE DNA Extraction Kit	The MP Diagnostics MPure FFPE DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA from FFPE (Formalin-Fixed, Paraffin-Embedded) tissue samples. It provides good quality, high integrity DNA for molecular diagnosis and research works.	Class A IVD, Rule 5
10	MP Diagnostics MPure Forensic DNA Extraction Kit	The MP Diagnostics MPure Forensic DNA Extraction Kit is used with the MPure-12 aNAP System for extraction of genomic DNA from forensic samples.	Class A IVD, Rule 5

THE SCHEDULE

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11	MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit A	The MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit A is used with the MPure-12 aNAP System for extraction of viral and bacterial DNA/RNA from cell-free samples, e.g. serum, plasma, and other cell-free body fluids.	Class A IVD, Rule 5
12	MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit B	The MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit B is used with the MPure-12 aNAP System for extraction of viral and bacterial DNA/RNA from swab samples (cell-rich samples).	Class A IVD, Rule 5
13	MP Diagnostics MPure Viral RNA Extraction Kit	The MP Diagnostics MPure Viral RNA Extraction Kit is used with the MPure-12 aNAP System for extraction of viral RNA from human biological specimens e.g. serum, plasma and other cell-free body fluids.	Class A IVD, Rule 5
14	MP Diagnostics MPure Viral Nucleic Acid Extraction Kit 800	The MP Diagnostics MPure Viral Nucleic Acid Extraction Kit 800 is used with the MPure-12 aNAP System for extraction of Viral DNA or RNA from human biological specimens such as serum, plasma, and other cell-free fluids.	Class A IVD, Rule 5
15	MP Diagnostics MPure-12 aNAP System	The MPure-12 aNAP System is a fully automated, standalone robot that can purify nucleic acids within 30-45 minutes. With advanced magnetic bead separation technology, it enables high quality extraction results. Moreover, the most user-friendly interface makes users free from troublesome parameter settings and maintenance.	Class A IVD, Rule 5

system



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16	MP Diagnostics DNA/RNA Extraction Kit	MP Diagnostics DNA/RNA Extraction Kit is intended for extraction and purification of total RNA/DNA from clinical materials (peripheral blood plasma, cerebrospinal and amniotic fluid, nasal and oropharyngeal swabs, and saliva).	Class A IVD, Rule 5
17	MP Diagnostics DNA Extraction Kit	MP Diagnostics DNA Extraction Kit is intended for the extraction and purification of DNA from clinical materials (scrapes and discharges of urogenital tract, throat, rectum, conjunctiva, erosions, ulcers; urine).	Class A IVD, Rule 5

END OF PRODUCT LIST



APPENDIX I

1. MP Diagnostics MPure Blood DNA Extraction Kit 200

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Blood DNA Extraction Kit 200	8AH40-048

2. MP Diagnostics MPure Blood DNA Extraction Kit 1200

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Blood DNA Extraction Kit 1200	8AH50-048

3. MP Diagnostics MPure Viral Nucleic Acid Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Viral Nucleic Acid Extraction Kit	8AH60-048

4. MP Diagnostics MPure Tissue DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Tissue DNA Extraction Kit	8AH70-048

5. MP Diagnostics MPure Cultured Cell DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Cultured Cell DNA Extraction Kit	8AH80-048

6. MP Diagnostics MPure Bacterial DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Bacterial DNA Extraction Kit	8AH90-048

7. MP Diagnostics MPure HPV DNA Extraction Kit for Swab Sample

S/No	Model/Description	Product Number
1	MP Diagnostics MPure HPV DNA Extraction Kit for Swab Sample	8AJ10-048



Certificate No.
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APPENDIX I

8. MP Diagnostics MPure TB DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure TB DNA Extraction Kit	8AJ20-048

9. MP Diagnostics MPure FFPE DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure FFPE DNA Extraction Kit	8AJ30-048

10. MP Diagnostics MPure Forensic DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Forensic DNA Extraction Kit	8AJ40-048

11. MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit A

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit A	8AJ50-048

12. MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit B

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Viral/Pathogen Nucleic Acids Extraction Kit B	8AJ60-048

13. MP Diagnostics MPure Viral RNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Viral RNA Extraction Kit	8AJ70-048

14. MP Diagnostics MPure Viral Nucleic Acid Extraction Kit 800

S/No	Model/Description	Product Number
1	MP Diagnostics MPure Viral Nucleic Acid Extraction Kit 800	8AK10-048

15. MP Diagnostics MPure-12 aNAP System

S/No	Model/Description	Product Number
1	MP Diagnostics MPure-12 aNAP System	EMC017



Certificate No.
FSC/167/2017

APPENDIX I

16. MP Diagnostics DNA/RNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics DNA/RNA Extraction Kit	8AH20-100

17. MP Diagnostics DNA Extraction Kit

S/No	Model/Description	Product Number
1	MP Diagnostics DNA Extraction Kit	8AH30-100

END OF PRODUCT LIST



VIỆT NAM