CONSULADO DE CHILE EN SINGAPUR

El Cónsul de Chile que suscribe certifica la autenticidad de la firma de don Khui Joo Ying
Ministerio RR.EE Singapur

Legalización N° 129/37 Arancel Art. N° 04/10
US$ 12-00
Singapur 04 de Abril de 2019

SINGAPORE ACADEMY OF LAW

# AUTHENTICATION CERTIFICATE

SERVICIO CONSULAR 2019 10 US$ CHILE
SERVICIO CONSULAR 2019 2 US$ CHILE

Néstor Guerrero S.
Consul de Chile

CONSULADO DE CHILE SINGAPUR

I hereby certify that –

Edmund Hendrick is a duly appointed Notary Public practising in Singapore, and that the signature appearing at the foot of the annexed Notarial Certificate dated 27th March 2019, is the signature of the said Edmund Hendrick.

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.

SINGAPORE ACADEMY OF LAW CERTIFICATION SEAL

Dated this 28th day of March 2019.

LAI WAI LENG
DEPUTY DIRECTOR
SINGAPORE ACADEMY OF LAW

19040073
Certified true signature
1 APR 2019
KHUI JOO YING

MINISTRY OF FOREIGN AFFAIRS SINGAPORE


1 Coleman Street, #08-06 The Adelphi, Singapore 179803
Tel: +65 6332 4388 | Fax: +65 6333 9747 | Website: http://www.sal.org.sg

# NOTARIAL CERTIFICATE

TO ALL TO WHOM THESE PRESENTS SHALL COME:

I **EDMUND HENDRICK**, **NOTARY PUBLIC**, duly authorized, appointed, admitted, sworn and practicing in the Republic of Singapore **DO HEREBY CERTIFY AND ATTEST** that attached hereto is the document described as "**CERTIFICATE OF A PHARMACEUTICAL PRODUCT**" bearing Original Certificate No. MCEL1900133 issued on 14 March 2019 and endorsed therein as having been signed by Dr CHOONG May Ling, Mimi of the Health Sciences Authority of the Republic of Singapore.

**IN FAITH AND TESTIMONY WHEREOF** I have hereunto subscribed my name and affixed my Seal of Office at Singapore this 27th day of March in the Year of Our Lord Two Thousand and Nineteen (2019).

Notary Public,
Singapore.

NOTARY PUBLIC
Edmund Hendrick
N2018/0102
1 Apr 2018 31 Mar 2019
SINGAPORE

REPUBLIC OF SINGAPORE
NOTARY PUBLIC

05CPF9

Health Sciences Authority
Republic of Singapore

**ORIGINAL**

CERTIFICATE NO.
**MCEL1900133**

# CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organisation

Exporting country: **SINGAPORE** Importing country: **CHILE**

Proprietary name (if applicable) and dosage form: **VYTORIN 10/10 TABLET**

Remarks: Not Applicable

Active ingredient(s) and amount(s) per unit dose: **Please see attached**

1. Is this product licensed to be placed on the market for use in the exporting country ? **Yes, please refer to box A**
2. Is this product actually on the market in the exporting country ? **Yes**

| **BOX A** |
|---|
| Product licence holder: **MSD PHARMA (SINGAPORE) PTE. LTD.**<br>**150 BEACH ROAD #31-00 GATEWAY WEST SINGAPORE 189720** |
| Status of product licence holder: **Neither Manufacturer Nor Packager** |
| Product licence number and date of issue: **SIN13011P** **18 Jun 2004** |
| Name & address of manufacturer of product:<br>**MSD INTERNATIONAL GMBH (SINGAPORE BRANCH)**<br>**21 TUAS SOUTH AVENUE 6 SINGAPORE 637766**<br>**Bulk Production** |
| Name & address of applicant for certificate if different from the licence holder:<br>**Not Applicable** |
| The summary basis of approval: **Not Appended** |
| The officially approved product information is complete and consonant with the licence:<br>**Not Provided** |

3. (a) Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the product is produced ? **Yes**
   (b) Periodicity of routine inspections (years): **At least once every 2 years**
   (c) Has the manufacture of this type of dosage form or product been inspected ? **Yes**
   (d) Do the facilities and operations conform to GMP as recommended by the World Health Organisation ? **Yes**
4. (a) Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party ? **Not Applicable**
   (b) If no, explain: **Not Applicable**

This certificate takes effect from **14 Mar 2019** and shall expire on **13 Mar 2021**

Date of issue: **14 Mar 2019**

Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way,#11-01 Helios,Singapore 138667
Tel: 65-68663522 Fax: 65-64789068
Email: HSA_Certification@hsa.gov.sg

106629

NOTARY PUBLIC
Edmund Hendrick
N2018/0102
1 Apr 2018 31 Mar 2019
SINGAPORE

Dr CHOONG May Ling, Mimi
for Licensing Authority

Health Sciences Authority
Republic of Singapore

Certificate No.

**MCEL1900133**

## THE SCHEDULE

| NAME OF PRODUCT | ALL INGREDIENT(S) | STRENGTH PER UNIT DOSE | REMARKS |
|---|---|---|---|
| VYTORIN 10/10 TABLET | SIMVASTATIN<br>EZETIMIBE | 10mg<br>10mg | |

Shelf –life: 24 months
Store below 30°C

Name and Address of Manufacturer:

MSD INTERNATIONAL GMBH (SINGAPORE BRANCH)
21 Tuas South Avenue 6
Singapore 637766

Ezetimibe 10 mg/Simvastatin 10 mg Combination Tablet—Market Composition

| Component | Reference | Function | mg/tablet |
|---|---|---|---|
| Simvastatin | USP, Ph. Eur. | Active | 10.00 |
| Ezetimibe | ---- | Active | 10.00 |
| Lactose Monohydrate | NF, Ph. Eur. | Filler | 58.23 |
| Microcrystalline Cellulose | NF, Ph. Eur. | Compression Aid | 15.00 |
| Hydroxypropyl Methylcellulose 2910 6 cps | USP, Ph. Eur. | Binder | 2.000 |
| Croscarmellose Sodium | NF, Ph. Eur. | Disintegrant | 3.000 |
| Ethyl Alcohol[†] | USP, Ph. Eur. | Granulating Fluid | ---- |
| Purified Water | USP, Ph. Eur. | Granulating Fluid | ---- |
| Citric Acid Monohydrate | USP, Ph. Eur. | Acidifier | 0.2500 |
| Butylated Hydroxyanisole | NF, Ph. Eur. | Antioxidant | 0.02000 |
| Propyl Gallate | NF, Ph. Eur. | Antioxidant | 0.005000 |
| Magnesium Stearate | NF, Ph. Eur. | Lubricant | 1.500 |
| Total Weight | | | 100.0 |

[†] Alternatively, DRAA Ethanol + 5 % methanol may be used, refer to **P.4 Control of Excipients.**