



CONSULADO DE CHILE EN
SINGAPUR

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

SINGAPORE ACADEMY OF LAW

Exposición N° 100/37 Arancel Art. N° 04/10

Fección 09 de Abril de 2019

AUTHENTICATION CERTIFICATE



Néstor Guerrero S.
Cónsul de Chile

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.

Dated this 28th day of March 2019.

Lai Wai Leng

LAI WAI LENG
DEPUTY DIRECTOR
SINGAPORE ACADEMY OF LAW

19040073

Certified true signature



Khui Joo Ying

KHUI JOO YING

1 APR 2019

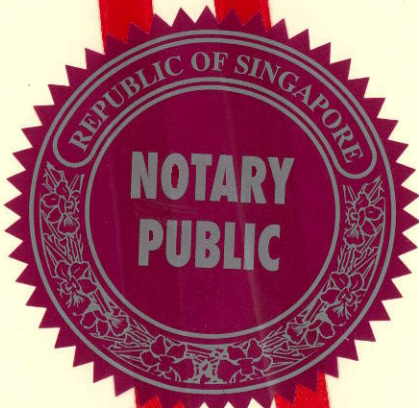
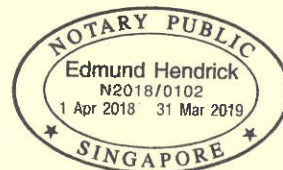
NOTARIAL CERTIFICATE

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.





Health Sciences Authority
Republic of Singapore

ORIGINAL

CERTIFICATE NO.

MCCL1900133

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. 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: MSD INTERNATIONAL GMBH (SINGAPORE BRANCH) 21 TUAS SOUTH AVENUE 6 SINGAPORE 637766 Bulk Production	
Name & address of applicant for certificate if different from the licence holder: Not Applicable	
The summary basis of approval: Not Appended	
The officially approved product information is complete and consonant with the licence: 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

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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 EZETIMIBE	10mg 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

HSA
Health Sciences Authority

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.



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