



NOTARIAL CERTIFICATE

TO ALL TO WHOM these presents shall come

I, Goh Phai Cheng, NOTARY PUBLIC duly admitted, authorised to practise in the Republic of Singapore, DO HEREBY CERTIFY

That the certified true copy of the Letter of **GOOD MANUFACTURING PRACTICE COMPLIANCE STATUS** dated **3 June, 2020** issued by DR. LAI WENG FAI, Director (Licensing & Certification Branch), Health Products Regulation Group, Health Sciences Authority of the Republic of Singapore hereunto annexed and marked "A" is a true and correct copy the same having been carefully examined and compared by me with the Original thereof on this day.

IN FAITH AND TESTIMONY whereof I the said notary have subscribed my name and set and affixed my seal of office at Singapore, this 3rd day of September 2020.

NOTARY PUBLIC
SINGAPORE



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| 2. This public document has been signed by: | Goh Phai Cheng |
| 3. Acting in the capacity of: | Notary Public |
| 4. Bears the seal/stamp: | Notary Public |

Certified

- | | |
|-----------------------------|----------------------------|
| 5. Authentication Cert No.: | AC0K6W0ATA |
| 6. At: | Singapore Academy of Law |
| 7. The: | 4th September 2020 |
| 8. By: | Low Hui Min, Director, SAL |

9. SAL Certification Seal:

10. Signature:



CONSULADO DE CHILE EN SINGAPUR

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

Actuación N° 164 Arancel Art. N° 09/10
US\$ 12-00/-
Singapur 09 de Septiembre de 2020

- 20090874

Certified true signature



Khui Joo Ying
08 SEP 2020



Néstor Guerrero S.
Consul de Chile



Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Website: www.hsa.gov.sg

HPRG(AB)16:01/3-17

03 June 2020

MSD International GmbH (Singapore Branch)
50 Tuas Drive, Singapore 638408

Attn: Mr Fernando Otero
Site Leader, MMD Singapore

Dear Mr Otero

GOOD MANUFACTURING PRACTICE COMPLIANCE STATUS

We refer to your company's application for a new GMP certificate (Application No. 19D8900M) and the subsequent correspondences.

2 MSD International GmbH (MSD) which is located at 50 Tuas West Drive Singapore 638408, is a manufacturer of chemical drug substances (as active pharmaceutical ingredients). The company holds a GMP Certificate, MCGM1700252, issued by the Health Sciences Authority, which attested its conformity to the Pharmaceutical Inspection Convention/Co-Operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products (Part II) and the relevant annexes in the manufacture of active pharmaceutical ingredients. The last inspection was conducted on 6 to 9 June 2017 and the GMP certificate remains valid until 5 June 2020.

3 MSD has submitted an application for a new GMP certificate and an on-site GMP inspection by the HSA was initially scheduled to take place from 21 April to 24 April 2020. In the light of the nation-wide implementation of Circuit Breaker measures on 7 April 2020 by the Government to mitigate the risk of transmission of Covid-19 infection, the HSA is mindful of the potential impact of an on-site GMP inspection on the health and safety of all personnel involved where safe distancing may be difficult to achieve.

4 Given the exceptional circumstances, the HSA has performed a desktop assessment in lieu of an on-site GMP inspection of MSD. From the knowledge gained in the assessment, MSD is deemed to be operating in continued compliance with the PIC/S GMP requirements while taking into considerations of the satisfactory history of compliance of MSD in the past inspections by the HSA. Notwithstanding, in relation to the pending application for a new GMP certificate, the HSA will conduct an on-site GMP inspection of MSD's manufacturing site at an appropriate time when the Covid-19 pandemic restrictions are lifted.

5 Additionally, we noted that MSD has been inspected recently by a number of PIC/S Participating Authorities including the Japan Pharmaceuticals and Medical Devices Agency (PMDA) and United States Food and Drug Administration (US FDA) with satisfactory outcome.

6 This letter reflects the status of the MSD's manufacturing site at the time of assessment noted above in paragraph 4 and the company's GMP compliance status remains valid for 12 months from the date of this letter.

7 Please contact the following personnel in the HSA if you need any further clarifications:

Ms Lim Na (Email: lim_na@hsa.gov.sg)

Ms Teo Seok Hui (Email: teo_seok_hui@hsa.gov.sg)

Yours sincerely



LAI WENG FAI (DR)
DIRECTOR (LICENSING & CERTIFICATION BRANCH)
for GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY



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