Notarial Act

CERTIFICATION OF TGA DOCUMENT

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Notarial Act

CERTIFICATION OF TGA DOCUMENT

I, **PHILIP MAXWELL EARLE**, Notary Public, practising in the City of Melbourne in the State of Victoria in the Commonwealth of Australia **DO HEREBY CERTIFY AND ATTEST** that:

1. **THERAPEUTIC GOODS ADMINISTRATION ("TGA")** is a unit of the Australian Government's Department of Health and is responsible for administering the provisions of the *Therapeutic Goods Act 1989* of the Commonwealth of Australia, the purpose of which is to provide a national framework for the regulation of therapeutic goods in Australia and to ensure their quality, safety and efficacy;
2. **PFIZER (PERTH) PTY LTD** is an approved TGA Australian Manufacturer bearing the licence No. MI-18102004-LI-000013-1. I have personally verified their licence via the TGA online portal.
3. The annexed copy document provided to me by **PFIZER (PERTH) PTY LTD** comprising 3 pages, all of which bear an impression of my official seal for purposes of identification, is a true copy of an electronic Certificate of GMP Compliance of a Manufacturer, Certificate No. MI-2019-LI-12128-1 issued on 12 November 2019 by TGA to **PFIZER (PERTH) PTY LTD**
4. Subject to paragraph 3, full faith and credit should be given to the contents of the copy documents, both in court and elsewhere.

IN WITNESS of which I have subscribed my name and affixed my Seal of Office this 23rd day of January 2020.

PHILIP MAXWELL EARLE
NOTARY PUBLIC
MELBOURNE
AUSTRALIA

Notary Public
My Appointment is not limited by time

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: **Australia**

This public document

2. has been signed by: **Philip Maxwell Earle**
3. acting in the capacity of: **Notary Public**
4. bears the seal/stamp of: **Philip Maxwell Earle, Notary Public, Melbourne**

Certified

5. at **Melbourne**
6. **the 28th day of January, 2020**
7. by **Silvia Leso**

Department of Foreign Affairs and Trade
Melbourne
Australia

8. No. **MFAF-95-97013**
9. Seal/Stamp
10. Signature

DEPT OF FOREIGN AFFAIRS AND TRADE * MELBOURNE *

This Apostille only certifies the authenticity of the signature (where applicable) and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. This Apostille can be verified at https://orao.dfat.gov.au/pages/verifyapostille.aspx

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-12128-1

Issued to:

Pfizer (Perth) Pty Ltd
ACN: 051 824 956

Manufacturing Site Address:

15 Brodie Hall Drive Technology Park
BENTLEY WA 6102
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-18102004-LI-000013-1** to manufacture therapeutic goods under section 38 of the *Therapeutic Goods Act 1989* and is included in the national inspection program following section 40(4)(b) of the *Therapeutic Goods Act 1989.*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10 to 14 December 2018, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 January 2017.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status after the expiry date. This certificate should also not be relied upon where the status of the Licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

EXPIRY DATE: 14 December 2021

ISSUE DATE: 12 November 2019

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-LI-12128-1

MANUFACTURING OPERATIONS

The manufacturer above is authorised under section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	Injections	Registered Therapeutic Good	Sterile Finished Product Manufacture
Medicine manufacture	Sterile	Injections	Registered Therapeutic Good	Parametric Release
Medicine manufacture	Sterile	Solution, irrigation	Registered Therapeutic Good	Sterile Finished Product Manufacture
Medicine manufacture	Sterile	Injections	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture
Medicine manufacture	Sterile	Injections	Therapeutic Goods for Clinical Trials	Parametric Release
Medicine manufacture	Sterile	Solution, irrigation	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture
Medicine manufacture	Non Sterile	Liquids Group	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Sterile	Liquids Group	Registered Therapeutic Good	Sterile Finished Product Manufacture
Medicine manufacture	Sterile	Semi Solids - Creams, Gels and Ointments	Registered Therapeutic Good	Sterile Finished Product Manufacture

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

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Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Semi Solids - Creams, Gels and Ointments	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Sterile	Semi Solids - Creams, Gels and Ointments	Registered Therapeutic Good	Parametric Release
Medicine manufacture	Sterile	Liquids Group	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture
Medicine manufacture	Non Sterile	Liquids Group	Therapeutic Goods for Clinical Trials	Finished Product Manufacture
Medicine manufacture	Sterile	Semi Solids - Creams, Gels and Ointments	Therapeutic Goods for Clinical Trials	Sterile Finished Product Manufacture
Medicine manufacture	Non Sterile	Semi Solids - Creams, Gels and Ointments	Therapeutic Goods for Clinical Trials	Finished Product Manufacture
Medicine manufacture	Sterile	Semi Solids - Creams, Gels and Ointments	Therapeutic Goods for Clinical Trials	Parametric Release

In addition to the statutory conditions that apply to all Licences granted under section 38 of the *Therapeutic Goods Act 1989*, the following specific conditions have been imposed on the Licence under sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

This licence authorises only the manufacture of medicines excepting preparations containing penicillins or cephalosporins.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

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