Te Tari Taiwhenua
Internal Affairs

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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   This public document
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2. has been signed by: Fiona Jane Mathieson
   a été signé par :
   ha sido firmado por:

3. acting in the capacity of: Notary Public
   agissant en qualité de :
   quien actúa en calidad de:

4. bears the seal / stamp of: Fiona Jane Mathieson
   est revêtu du sceau / timbre de :
   y está revestido del sello / timbre de:

Certified

Attesté / Certificado

5. at: Wellington
   à / en:

6. the: 25 October 2018
   le / el día:

7. by: The Authentication Unit
   par / por:

8. No: 04536.1
   sous n° / bajo el número:

9. Seal / Stamp:
   Sceau / Timbre :
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17 October 2018

TO WHOM IT MAY CONCERN

I, **ROGER SMART, REGULATORY and CLINICAL AFFAIRS STRATEGIC BUSINESS PARTNER** for **DOUGLAS MANUFACTURING LTD** herein after named **DOUGLAS,** a company organised and registered under the laws of New Zealand, am authorised by **DOUGLAS** to make the following statement:

The attached documentation is a true copy of the Certificate of Good Manufacturing Practice issued by SwissMedic to Swisscaps AG that is valid for the period March 14th 2017 to 13 March 2020.

ROGER SMART
Regulatory and Clinical Affairs Strategic Business Partner
For Douglas Manufacturing Ltd

Signature witnessed by:

I FIONA JANE MATHIESON, of Auckland Notary Public, hereby certify that I have witnessed the signature of Roger Smart **and I have hereunto subscribed my name and affixed my Seal of Office at Auckland this** 16th October 2018

FIONA JANE MATHIESON
SOLICITOR/NOTARY PUBLIC
AUCKLAND

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swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **SWISS CAPS AG** with its site **Husenstrasse 35, 9533 Kirchberg, Switzerland**, has been duly authorized to manufacture and distribute medicinal products and investigational medicinal products, the manufacturing licence excluding sterile products and including following dosage forms:

- liquid dosage forms (including highly active or sensitising products such as hormones, esters of fatty acids, Vitamine D Derivative and Retinoic)
- semi-solid dosage forms (including highly active or sensitising products such as hormones, esters of fatty acids, Vitamine D Derivative and Retinoic)
- solid dosage forms (including highly active or sensitising products such as hormones, esters of fatty acids, Vitamine D Derivative and Retinoic)

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **March 14-16, 2017**;

that the requirements regarding manufacture and quality control for pharmaceutical products for export are identical to those applicable to products sold in Switzerland.

Berne, June 20, 2017
No. 17-1190

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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