



Te Tari Taiwhenua Internal Affairs

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: New Zealand
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This public document
Le présent acte public / El presente documento público
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:
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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.

A handwritten signature in blue ink, appearing to read "Roger Smart".

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 have hereunto subscribed my name
and affixed my Seal of Office at Auckland
this *16th October 2018*

A handwritten signature in blue ink, appearing to read "Fiona Jane Mathieson".

FIONA JANE MATHIESON
SOLICITOR/NOTARY PUBLIC
AUCKLAND

Douglas Pharmaceuticals Ltd
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PO Box 45 027, Auckland 0651
New Zealand
T: +64 9 835 0660 F: +64 9 835 0665
www.douglas.co.nz

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**;

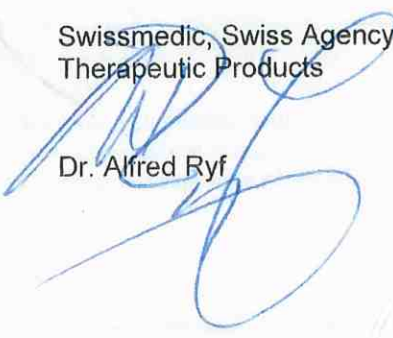
that the requirements regarding manufacture and quality control for pharmaceutical products for export are identical to those applicable to products sold in Switzerland.

Berne, June 20, 2017
No. 17-1190



Swissmedic, Swiss Agency for
Therapeutic Products

Dr. Alfred Ryf

A large, stylized blue ink signature of Dr. Alfred Ryf, written over the text "Dr. Alfred Ryf".