

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Dr. Heinz Welti AG, Fabrikation chemisch-pharmazeutischer Produkte, Wiesenstrasse 21, 5412 Gebenstorf** with its site **Dr. Heinz Welti AG, Fabrikation chemisch-pharmazeutischer Produkte, Hauptstrasse 163, 4416 Bubendorf, Switzerland**, has been duly authorized to manufacture and distribute medicinal products and investigational medicinal products;

that the company is manufacturing the following dosage forms:

- liquid dosage forms
- semi-solid dosage forms
- solid dosage forms
- investigational medicinal products

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 medicinal products and investigational medicinal 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 **August 30-31, 2017**;

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

Berne, February 27, 2018
No. 18-0433

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Georges Meseguer

