swissmedic

CERTIFICATE OF GMP COMPLIANCE

(for the Health Authorities of Germany in the frame of the MRA between Switzerland and the European Community, Chapter 15 on Medicinal Products)

We certify herewith

that the company **Microsynth AG, Schützenstrasse 15, 9436 Balgach, Switzerland**, has been duly authorized to manufacture medicinal products, the manufacturing licence including following activities:

- Quality control (chemical, physical and biochemical) of medicinal products as contract laboratory
- Quality control (biological) of medicinal products as contract laboratory

The activities are restricted to the DNA sequencing with the Sanger method

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products and active pharmaceutical ingredients 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 inspection was conducted on **February 16, 2016**;

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

Berne, April 20, 2016
No. 16-0427

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Georges Meseguer

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

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12