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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Merck & Cie, Weisshausmatte, 6460 Altdorf UR, Switzerland** with its site **Im Laternenacker 5, 8200 Schaffhausen, Switzerland**, has been duly authorized to manufacture and distribute investigational medicinal products and active pharmaceutical ingredients, the manufacturing licence excluding sterile products and including following activities:

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

including following packaging activities:
- Packaging of 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 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 regular inspection was conducted on **March 24-26, 2015**;

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, June 22, 2015
No. 15-1287

Swiss Agency for Therapeutic Products
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Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

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