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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Cilag AG, Hochstrasse 201, 8200 Schaffhausen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, medicinal products and investigational medicinal products;

that the manufacturing licence is including following types of active pharmaceutical ingredients (APIs):

- highly active or sensitising APIs such as cytostatics
- investigational active pharmaceutical ingredients

that the company is manufacturing the following dosage forms:

- liquid dosage forms including aseptically prepared forms and highly active or sensitising APIs such as hormone and cytostatics
  - biological products such as
    - APIs, bulk and medicinal products from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
    - APIs, bulk and medicinal products produced by means of recombinant technologies, hybridoma and monoclonal antibodies

- solid dosage forms including aseptically prepared forms
  - biological products such as
    - APIs, bulk and medicinal products from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
    - APIs, bulk and medicinal products produced by means of recombinant technologies, hybridoma and monoclonal antibodies

- investigational medicinal products
  - including solid dosage forms
  - including liquid dosage forms
  - aseptically prepared forms

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

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that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, 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 **November 28-30, 2017**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, medicinal products and investigational medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, medicinal products and investigational medicinal products sold in Switzerland.

Berne, March 12, 2018
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Swiss Agency for Therapeutic Products
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Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

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