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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Osmopharm SA, Via alle Fornaci, 6930 Bedano, Switzerland**, has been duly authorized to manufacture and distribute medicinal products and investigational medicinal products;

that the company is manufacturing the following dosage forms:

- solid dosage forms
- investigational medicinal products
  - including solid dosage forms
  - including randomisation

that the company is performing the following activities:

- secondary packing of medicinal products including randomisation of medicinal products for clinical trials

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 **April 10-11 2018**;

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, June 4, 2018
No. 18-1130

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products
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