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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Rivopharm SA, 6928 Manno** with its site **Rivopharm SA, Centro Insema, 6928 Manno, 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

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 **May 14-15, 2019**;

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, July 22, 2019
No. 19-1010

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products
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