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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Medistri SA, Belmont-Broye** with its site **Medistri SA, Route de l'industrie SA 96, 1564 Domdidier, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

that the company is performing the following activities:

- secondary packing of medicinal products includes the sterilization with ethylene oxide of the external surface of glass vials containing sterile injectable solutions

- quality control (chemical, physical) 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

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and 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 **February 28, 2019**;

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

Berne, July 10, 2020
No. 20-0396

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

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