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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Synergy Health Däniken AG, Hogenweidstrasse 6, 4658 Däniken, Switzerland**, has been duly authorized **to sterilize by gamma or x-rays irradiation** following categories of products:

active pharmaceutical ingredients (APIs):

- APIs produced aseptically
- APIs terminally sterilised
- highly active or sensitising APIs
- biological APIs such as
  - immunological active pharmaceutical ingredients (as vaccine, sera, allergen)
  - APIs from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
  - APIs produced by means of recombinant technologies, hybridoma and monoclonal antibodies
  - APIs (extracts) of human or animal origin
- investigational active pharmaceutical ingredients

dosage forms:

- liquid dosage forms including aseptically prepared forms, terminally sterilised forms, highly active or sensitising APIs and biological products such as
  - immunological medicinal products (as vaccine, sera, allergen)
  - medicinal products from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
  - medicinal products produced by means of recombinant technologies, hybridoma and monoclonal antibodies
  - medicinal products with APIs (extracts of human or animal origin)

- semi-solid dosage forms including aseptically prepared forms, terminally sterilised forms, highly active or sensitising APIs and biological products such as
  - immunological medicinal products (as vaccine, sera, allergen)
  - medicinal products from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
  - medicinal products produced by means of recombinant technologies, hybridoma and monoclonal antibodies
  - medicinal products with APIs (extracts of human or animal origin)

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- solid dosage forms including aseptically prepared forms, terminally sterilised forms, highly active or sensitising APIs and biological products such as
  - immunological medicinal products (as vaccine, sera, allergen)
  - medicinal products from human blood and blood plasma (as albumin, IgG, blood-clotting proteins)
  - medicinal products produced by means of recombinant technologies, hybridoma and monoclonal antibodies
  - medicinal products with APIs (extracts of human or animal origin)

- investigational medicinal products
  - including solid dosage forms
  - including semi-solid dosage forms
  - including liquid dosage forms
  - aseptically prepared forms
  - terminally sterilised forms

- medicated feedstuffs

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 active pharmaceutical ingredients (APIs), investigational active pharmaceutical ingredients, medicinal products, investigational medicinal products and medicated feedstuffs 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 **January 28-29, 2020**;

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

Berne, August 13, 2020
No. 20-0497

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Georges Meseguer

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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