

CERTIFICATE OF GMP COMPLIANCE

(for Canadian Health Authorities in the frame of the MRA between Switzerland and Canada,
Sectoral Annex on Medicinal Products)

We certify herewith

that the company **Emott AG, 8600 Dübendorf** with its site **Emott AG, In Grosswiesen 14, 8044 Gockhausen, Switzerland**, has been duly authorized to manufacture medicinal products, the manufacturing licence including following activities:

- Quality control (chemical, physical and biochemical) of medicinal products as contract laboratory
- Quality control (biological) of medicinal products as contract laboratory

that the company is keeping the required level for good practices in the manufacture of pharmaceutical products and active pharmaceutical ingredients 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 inspection was conducted on **August 11, 2016**;

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

Berne, February 13, 2017
No. 17-0272

Swissmedic, Swiss Agency for
Therapeutic Products




Dr. Georges Meseguer