

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **M. Opitz & Co. AG**, Haggenstrasse 40, 9014 St. Gallen, Authorisation No. 511410-102610229 with its site **M. Opitz & Co. AG**, Haggenstrasse 40, 9014 St. Gallen, Switzerland, Site No. 1005110 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) 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) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **27.02.2019** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.2	Non-sterile products	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.5	Liquids for external use	H/V
1.2.1.6	Liquids for internal use	H/V
1.2.1.11	Semi-solids	H/V
1.2.2	Batch certification (technical release)	H/V
1.4	Other products or manufacturing activity	
1.4.1	Manufacture of:	
1.4.1.1	Herbal products	H/V
1.4.1.2	Homoeopathic products	H/V
1.5	Packaging	
1.5.1	Primary packing	
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.1.11	Semi-solids	H/V
1.5.2	Secondary packing	H/V

* Scope of authorisation:

- H/V Human and veterinary medicinal products, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified

Berne, 09.10.2019 (dd.mm.yyyy)
No. GMP-CH-1000510

Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Georges Meseguer

A handwritten signature in blue ink, appearing to read "G. Meseguer", is written over the printed name.

SWISSmedic