



CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Ivers-Lee AG, Kirchbergstrasse 160, 3400 Burgdorf**, Authorisation No. 511246-102637948 with its site **Ivers-Lee AG, Kirchbergstrasse 160, 3400 Burgdorf, Switzerland**, Site No. 1001392 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 **05.08.2020** (dd.mm.yyyy).

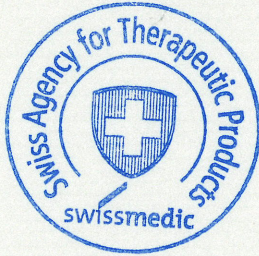
No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.5	Packaging	
1.5.1	Primary packing	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.2	Capsules, soft shell	H/V, I
1.5.1.3	Chewing gums	H/V, I
1.5.1.8	Other solid dosage forms	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packing	H/V, I
1.6	Quality control testing	
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
S.1.8	Blinding of medicinal products for clinical trials	

* 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, **07.12.2020** (dd.mm.yyyy)
No. GMP-CH-1001614

Swissmedic, Swiss Agency for
Therapeutic Products



J. Büchi

Jacqueline Büchi

SWISSmedic