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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Laboratorium Dr. G. Bichsel AG, Weissenaustrasse, 3800 Unterseen,** Authorisation No. 512031-102643475 with its site **Laboratorium Dr. G. Bichsel AG, Weissenaustrasse 73, 3800 Unterseen, Switzerland,** Site No. 1004788 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 **22.06.2021** (dd.mm.yyyy).

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
1.1.1.1	Large volume liquids	I
1.1.1.3	Semi-solids	I
1.1.1.4	Small volume liquids	I
1.1.2	Terminally sterilised (processing operations for the following dosage forms)	
1.1.2.1	Large volume liquids	H/V, I
1.1.2.2	Semi-solids	I
1.1.2.3	Small volume liquids	H/V, I
1.1.3	Batch certification (technical release)	H/V, I
1.2	**Non-sterile products**	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.1	Capsules, hard shell	H/V, I
1.2.1.11	Semi-solids	I
1.2.1.13	Tablets	I
1.2.2	Batch certification (technical release)	H/V, I
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	
1.3.1.8	Other biological medicinal products: Heparin	H/V, I
1.3.2	Batch certification (technical release)	
1.3.2.8	Other biological medicinal products: Heparin	H/V, I
1.4	**Other products or manufacturing activity**	
1.4.2	Sterilisation of active substances / excipients / finished product	
1.4.2.1	Filtration	I
1.4.2.3	Moist heat	H/V, I

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No.	Operation	Scope*
1.4.2.4	Chemical	I
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.2	Capsules, soft shell	H/V, I
1.5.1.5	Liquids for external use	H/V, I
1.5.1.6	Liquids for internal use	H/V, I
1.5.1.11	Semi-solids	I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packaging	H/V, I
1.6	**Quality control testing**	
1.6.1	Microbiological: sterility	H/V, I
1.6.2	Microbiological: non-sterility	H/V, I
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, **21.09.2021** (dd.mm.yyyy)
No. GMP-CH-1002534

Swissmedic, Swiss Agency for Therapeutic Products

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Luxshana Santhirasegarar