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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Laboratorium Dr. G. Bichsel AG, Weissenaustrasse 73, 3800 Unterseen,** Authorisation No. 512031-102718998 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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **22.06.2021** (dd.mm.yyyy), it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada/USA and Switzerland;

that this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in SwissGMDP/EudraGMDP. If it does not appear, please contact the issuing authority.

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.2	Terminally sterilised (processing operations for the following dosage forms)	
1.1.2.1	Large volume liquids	H/V,I
1.1.2.3	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	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

No.	*Operation*	*Scope**
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	I
1.5.1.6	Liquids for internal use	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

* 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

Bern, **01.02.2024** (dd.mm.yyyy)

No. GMP-CH-1005415

Swissmedic, Swiss Agency for Therapeutic Products.