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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Osmopharm SA, Via alle Fornaci, 6930 Bedano,** Authorisation No. 511405-102638022 with its site **Osmopharm SA, Via alle Fornaci, 6930 Bedano, Switzerland,** Site No. 1000764 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 **13.07.2022** (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)	
1.2.1.1	Capsules, hard shell	H/V, I
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.13	Tablets	H/V, I
1.2.1.16	Veterinary premixes	H/V
1.2.2	Batch certification (technical release)	H/V, I
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.1.16	Veterinary premixes	H/V
1.5.2	Secondary packaging	H/V, I
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	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

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Berne, **26.09.2022** (dd.mm.yyyy)
No. GMP-CH-1003541

Swissmedic, Swiss Agency for Therapeutic Products

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