

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **FONDATION POLYVAL** , , **1000 Lausanne**, Authorisation No. 511553-102614898 with its site **FONDATION POLYVAL Site de Vernand** , **Route des Dragons 9, 1033 Cheseaux sur Lausanne, Switzerland**, Site No. 1102327 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 **02.11.2018** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.5	Packaging	
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, **04.10.2019** (dd.mm.yyyy)
No. GMP-CH-1000497

Swissmedic, Swiss Agency for
Therapeutic Products




Dr. Georges Meseguer

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **FONDATION POLYVAL** , , **1000 Lausanne**, Authorisation No. 511553-102614898 with its site **FONDATION POLYVAL Site de Nyon , Route de Divonne 48, 1260 Nyon, Switzerland**, Site No. 1003083 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;

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