

## CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company Centre hospitalier universitaire vaudois (CHUV), Rue du Bugnon 21, 1011 Lausanne, Authorisation No. 511133-102637946 with its site Centre hospitalier universitaire vaudois (CHUV), Service de pharmacie, Rue du Bugnon 46, 1011 Lausanne, Switzerland, Site No. 1100213 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;

that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) of the European Commission and with the requirements of the European GMP Part II (Basic Requirements for Active Substances used as Starting Materials);

that the company is subject to official periodic inspections; the last regular inspection has been performed on **16.10.2020** (dd.mm.yyyy).

| No.   | Operation   |
|---|---|
| S.2   | IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)  |
| S.2.1   | Import of non- ready-to-use medicinal products  |
| S.2.1.1<br>S.2.1.2<br>S.2.1.3                         | Medicinal products (without immunological and blood products) Immunological products Blood products   |
| S.2.3   | Import of ready-to-use medicinal products, excluding market release   |
| S.2.3.1<br>S.2.3.2<br>S.2.3.3<br>S.2.3.4<br>S.2.3.4.1 | Medicinal products (without immunological and blood products) Immunological medicinal products Blood products The import for ready-to-use medicinal products, excluding market release, is restricted to: |
| S.2.3.4.3   | the import for exclusive re-export<br>the import of preparations not authorised in Switzerland on behalf of the ordering healthcare<br>professional   |
| S.2.3.4.4   | the import of medicinal products for clinical trials on behalf of the sponsor for subsequent distribution to the trial centres  |
| S.2.6   | Outsourcing of manufacture of medicinal products as contract giver  |
| S.4   | WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)  |
| S.4.1   | Wholesale distribution of non- ready-to-use medicinal products  |
| S.4.1.1<br>S.4.1.2<br>S.4.1.3                         | Medicinal products (without immunological and blood products) Immunological products Blood products   |
| S.4.3   | Wholesale distribution of ready-to-use medicinal products, excluding market release   |
| S.4.3.1   | Medicinal products (without immunological and blood products)   |



| Operation  |   |
|--|---|
| Immunological products Blood products  | 7   |
| Outsourcing of manufacture of medicinal products as contract giver                   |   |
| EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)                         |   |
| Export of non- ready-to-use medicinal products                                       |   |
| Medicinal products (without immunological and blood products) Immunological products |   |
| Export of ready-to-use medicinal products  |   |
| Medicinal products (without immunological and blood products) Immunological products |   |
|  | Immunological products Blood products Outsourcing of manufacture of medicinal products as contract giver EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)  Export of non- ready-to-use medicinal products Medicinal products (without immunological and blood products) Immunological products  Export of ready-to-use medicinal products Medicinal products (without immunological and blood products) |

Berne, **17.12.2020** (dd.mm.yyyy) **No. GDP-CH-1001662** 

Swissmedic, Swiss Agency for Therapeutic Products



Marianne Baumann

