Regierungspräsidium Tübingen

CERTIFICATE NUMBER: ***DE_BW_01_GMP_2020_0158***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Germany confirms the following:
The manufacturer: ***Rentschler Biopharma SE***
Site address: ***Erwin-Rentschler-Strasse 21, Laupheim, Baden-Wuerttemberg, 88471, Germany***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BW_01_MIA_2020_0106*** in accordance with Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-06-24***, it is considered that it complies with:

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products

Clarifying remarks (for public users)

Certificate for the manufacturing activities mentioned under 1.1 and 1.3 will be given for a limited period until December 31, 2020. Ad 1.3.1.5: Medicinal product, biotechnological origin: recombinant proteins, monoclonal antibodies, cytokines. Including batch release and quality control of the manufactured products - including the Manufacturer's Authorisation DE_BW_01_MIA_2020_0107, dated November 18, 2020 and GMP-Certificate DE_BW_01_GMP_2020_0157, dated December 02, 2020.

2020-12-02

Name and signature of the authorised person of the Competent Authority of Germany

---

Confidential
Regierungspräsidium Tübingen
Tel:***Confidential***
Fax:***Confidential***