Government of Upper Franconia

CERTIFICATE NUMBER: ***DE_BY_05_GMP_2022_0092***

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

Part 1

Issued following an inspection in accordance with :
Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Germany confirms the following:
The manufacturer: ***Labor LS SE & Co. KG***
Site address: ***Mangelsfeld 4-6Grossenbrach, Bad Bocklet, Bavaria, 97708***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011865*** / ***LOC-100018825***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BY_05_MIA_2022_0077*** in accordance with Art. 88 of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-12-14***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

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.

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[1] *The certificate referred to in paragraph Art. 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

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

The manufacturing authorisation is restricted to veterinary medicinal products which have been tested and released by the manufacturer Labor LS SE & Co. KG as a subcontractor.

2022-12-19

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

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Confidential
Regierung von Oberfranken
Tel: ***Confidential***
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