MANUFACTURER'S AUTHORISATION [1] , [2]

1. Authorisation Number	DE_BY_05_MIA_2022_0050
2. Name of authorisation holder	Labor Ls SE & Co. KG (ORG-100011865 / LOC-100018825)
3. Address(es) of manufacturing site(s)	Labor Ls SE & Co. KG (ORG-100011865 / LOC-100018825), Mangelsfeld 4-6Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany
4. Legally registered address of authorisation holder	Mangelsfeld 4-6Grossenbrach, Bad Bocklet, Bavaria, 97708
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2022-08-16
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Labor Ls SE & Co. KG, Mangelsfeld 4-6Grossenbrach, Bad Bocklet, Bavaria, 97708, Germany

Additional Details:

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS(according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 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*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

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

Part 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*