MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_BW_01_MIA_2019_0039
2. Name of authorisation holder	Lexamed GmbH
3. Address(es) of manufacturing site(s)	Lexamed GmbH, Thujaweg 1, Karlsruhe, Baden-Wuerttemberg, 76149, Germany
4. Legally registered address of authorisation holder	Thujaweg 1, Karlsruhe, Baden-Wuerttemberg, 76149, Germany
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	2019-05-09
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 : Lexamed GmbH, Thujaweg 1, Karlsruhe, Baden-Wuerttemberg, 76149, Germany

Human Medicinal Products

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

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: Cannabis flowers and Cannabis extracts in oily solution(en)
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

This license is based on the Site Master File dated July 23, 2018. Importation, batch certification and distribution are limited to Cannabis flowers and Cannabis extracts in oily solution. Quality control activities are performed at the laboratory in Appenweier.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

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

This license is based on the Site Master File dated July 23, 2018. Importation, batch certification and distribution are limited to cannabis flowers and Cannabis extracts in oily solution. Quality control activities are performed at the laboratory in Appenweier.