

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_BW_01_MIA_2019_0122
2. Name of authorisation holder BBF Sterilisationservice GmbH
3. Address(es) of manufacturing site(s) BBF Sterilisationservice (ORG-100011984 / LOC-100022480),
Willy-Ruesch-Strasse 10/1, Kernen, Baden-Wuerttemberg, 71394,
Germany
4. Legally registered address of authorisation holder Willy-Ruesch-Strasse 10/1, Kernen, Baden-Wuerttemberg, 71394
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
Art. 44 of Directive 2001/82/EC
Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2019-12-18
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

¹The 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.

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

³The 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: BBF Sterilisationsservice, Willy-Ruesch-Strasse 10/1, Kernen,
Baden-Wuerttemberg, 71394, Germany

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.5 Gamma irradiation
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i>

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

Manufacturing authorisation is granted for the rooms and buildings specified in the Site Master File, dated 05.12.2019.

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : BBF Sterilisationsservice, Willy-Ruesch-Strasse 10/1, Kernen,
Baden-Wuerttemberg, 71394, Germany

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.4	Other products or manufacturing activity
	<i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.5 Gamma irradiation
1.6	Quality control testing
	1.6.1 Microbiological: sterility

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

Manufacturing authorisation is granted for the rooms and buildings specified in the Site Master File, dated 05.12.2019.