

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_BW_01_MIA_2019_0122/DE_BW_01_BBF Sterilisationsservice
2. Name of authorisation holder	BBF Sterilisationsservice GmbH
3. Address(es) of manufacturing site(s)	BBF Sterilisationsservice Willy-Rüsch-Straße 10/1 71394 Kernen
4. Legally registered address of authorisation holder	Willy-Rüsch-Straße 10/1 71394 Kernen
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Reinhard Kerker
8. Signature	
9. Date	18/12/2019
10. Annexes attached	Annex 1 and Annex 2

SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

BBF Sterilisationservice, Willy-Rüsch-Straße 10/1, 71394 Kernen

Human Medicinal Products Veterinary Medicinal Products

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 substances/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

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-Rüsch-Straße 10/1, 71394 Kernen

Investigational Medicinal Products for Human Use
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AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

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

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

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