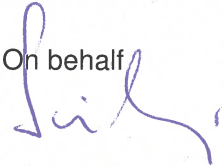




Bezirksregierung Detmold  
Leopoldstr. 15  
32756 Detmold

## MANUFACTURER'S AUTHORISATION

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

- |  |   |
|--|---|
| 1. Authorisation number/file number  | DE_NW_02_MIA_2020_0026/24.05.01-018   |
| 2. Name of authorisation holder  | AxioNovo GmbH   |
| 3. Address(es) of manufacturing site(s)  | AxioNovo GmbH<br>Kammerichstrasse 39<br>33647 Bielefeld   |
| 4. Legally registered address of authorisation holder  | Kammerichstrasse 39<br>33647 Bielefeld  |
| 5. Scope of authorisation and dosage forms   | ANNEX 1 and ANNEX 2   |
| 6. Legal basis of authorisation  | Sect 13 para 1 and sect 72 para 1<br>Arzneimittelgesetz (German Drug Law)                         |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Martin Sieling  |
| 8. Signature   | On behalf<br> |
| 9. Date  | 20/11/2020  |
| 10. Annexes attached   | Annex 1 and Annex 2   |



**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

AxioNovo GmbH, Kammerichstrasse 39, 33647 Bielefeld

Human Medicinal Products
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

**Part 1 - MANUFACTURING OPERATIONS**

<b>1.1</b>	<b>Sterile Products</b>
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	<i>1.1.3 Batch certification</i>
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<b>1.2</b>	<b>Non-sterile products</b>
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	<i>1.2.2 Batch certification</i>
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<b>1.5</b>	<b>Packaging</b>
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	<i>1.5.2 Secondary packing</i>
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<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>



**SCOPE OF AUTHORISATION**

Name and address of the site:

AxioNovo GmbH, Kammerichstrasse 39, 33647 Bielefeld

Investigational Medicinal Products for Human Use
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<b>AUTHORISED OPERATIONS</b> Manufacturing Operations (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>

