




Bezirksregierung Detmold
Leopoldstr. 15
32756 Detmold

MANUFACTURER'S AUTHORISATION

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

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| 1. Authorisation number/file number | DE_NW_02_MIA_2023_0018/24.05.01-018 |
| 2. Name of authorisation holder | AxioNovo GmbH
(LOC-100001914) |
| 3. Address(es) of manufacturing site(s) | AxioNovo GmbH
Kammerichstrasse 39
33647 Bielefeld
(LOC-100001914) |
| 4. Legally registered address of authorisation holder | Kammerichstrasse 39
33647 Bielefeld |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
Sect 72 para 1 Arzneimittelgesetz (German Drug Law) |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Dr. Stephanie Kottmann |
| 8. Signature | On behalf
 |
| 9. Date | 02/10/2023 |
| 10. Annexes attached | Annex 1 |



SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AxioNovo GmbH, Kammerichstrasse 39, 33647 Bielefeld

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
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>



Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<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>

