


MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_RP_01_MIA_2026_0001/3112-0063/20260203
2. Name of authorisation holder	DMB Apparatebau GmbH (LOC-100052314)
3. Address(es) of manufacturing site(s)	DMB Apparatebau GmbH Spiesheimer Weg 25a 55286 Wörrstadt (LOC-100052314)
4. Legally registered address of authorisation holder	Spiesheimer Weg 25a 55286 Wörrstadt
5. Scope of authorisation and dosage forms	ANNEX 1
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	
8. Signature	On behalf
9. Date	03/02/2026
10. Annexes attached	Annex 1 Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

DMB Apparatebau GmbH, Spiesheimer Weg 25a, 55286 Wörrstadt

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.4 Other products or manufacturing activity***1.4.2 Sterilisation of active substances/excipients/finished product*

1.4.2.4 Chemical

1.6 Quality control testing*1.6.3 Chemical/Physical*

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

Item 1.4.2.4

- Ethylene Oxide - Sterilisation of finished medicinal products (see Annex 8)

Name(s) of Qualified Person(s)

[REDACTED]

[REDACTED]

Deputy Qualified Person

Date of Inspection on which
authorisation was granted

13/01/2026

Products authorised to be manufactured (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

- Sterilisation von gentamicinhaltigen Kollagenschwämmen (s. Produktliste vom 05.05.2020) /
Sterilization of Gentamicin-containing collagen sponges (see list of products, dated May 05, 2020)