## 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\_2023\_0007/54.3/DMB/20230308

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 and ANNEX 2

6. Legal basis of authorisation

Sect 13 para 1 Arzneimittelgesetz (German Drug

Law)

Art. 61 para 1 to 3 of Regulation (EU) No.

536/2014 in conjunction with Sect 13 para 5 AMG

7. Name of responsible officer of the competent authority of the member state granting the

manufacturing authorisation

Dr. Ilka Petry

8. Signature

On behalf

9. Date

08/03/2023

10. Annexes attached

Annex 1 and Annex 2

Annex 4 (Addresses of Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 7 (Date of inspection on which authorisation