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_2025_0008/DE_BW_01_Deltamedica

2. Name of authorisation holder Deltamedica

GmbH

(LOC-100010731)

3. Address(es) of manufacturing site(s) Deltamedica GmbH

Ernst-Wagner-Weg 1-5 72766 Reutlingen (LOC-100010731)

4. Legally registered address of

authorisation holder

Ernst-Wagner-Weg 1-5 72766 Reutlingen

5. Scope of authorisation and dosage forms ANNEX 1

6. Legal basis of authorisation

Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Art. 88 of Regulation (EU) 2019/6 and Sect 28 para 1

German Veterinary Medicinal Products Law

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

Dr. Marcel Günther

8. Signature

9. Date 21/01/2025

10. Annexes attached Annex 1

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site: Deltamedica GmbH, Ernst-Wagner-Weg 1-5, 72766 Reutlingen

Human Medicinal Products	
Veterinary Medicinal Products	

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	Sterile Products
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.2 Batch certification