




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_SL_01_MIA_2024_0029/5000-110#002 |
| 2. Name of authorisation holder | hvd medical GmbH
(LOC-100019222) |
| 3. Address(es) of manufacturing site(s) | hvd medical GmbH
Carl-Zeiss-Straße 30
66740 Saarlouis
(LOC-100019222) |
| 4. Legally registered address of authorisation holder | Carl-Zeiss-Straße 30
66740 Saarlouis |
| 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 | Dr. Thomas Rohn |
| 8. Signature | On behalf  |
| 9. Date | 16/09/2024 |
| 10. Annexes attached | Annex 1
Annex 5 (Name of Qualified Person)
Annex 6 (Name of responsible persons)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

hvd medical GmbH, Carl-Zeiss-Straße 30, 66740 Saarlouis

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS
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1.5	Packaging
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	<i>1.5.2 Secondary packing</i>
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Exclusive manufacturing does not include import. The manufacturing authorization covers the packaging, labeling and release of medicinal products which have been reimported and parallel.
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Name(s) of Qualified Person(s)

Mr. Dr. Frank Ullrich

Mr. Christoph Henke

Deputy

Name(s) of person(s) responsible for
quality control

Mrs. Alice Barthel

Mr. Christoph Henke

Dputy

Name(s) of person(s) responsible for
production

Mrs. Petra Augustin

Mr. Dr. Frank Ullrich

Deputy

Annex 7

Date of Inspection on which
authorisation was granted

07/04/2022

Scope of last Inspection

look for the inspectionreport