



SAARLAND

Ministerium für Soziales, Gesundheit, Frauen und Familie

“English Translation/Original in German”

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

1. Authorisation number

DE_SL_01_WDA_2020_005/5011-027

2. Name of authorisation holder

hvd medical GmbH

3. Legally registered address of authorisation holder

Carl-Zeiss-Str. 30

66740 Saarlouis

4. Address(es) of site(s)

See Annex 1

5. Scope of authorisation (complete for each site under 4)

See Annex 1

6. Legal basis of authorisation

Section 52a para 1 German Drug Law/ Art. 11 (1) of 2001/83/EC

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

Stefan Stein

8. Signature

9. Date

Saarbrücken, 2020-02-26

10. Annexes attached:

- | | | |
|-------------------------------------|---------|--|
| <input checked="" type="checkbox"/> | Annex 1 | Scope of wholesale distribution authorisation |
| <input type="checkbox"/> | Annex 2 | (Optional) Address(es) of contract wholesale distribution sites and their authorisation number |
| <input checked="" type="checkbox"/> | Annex 3 | (Optional) Name(s) of responsible person(s) |
| <input type="checkbox"/> | Annex 4 | (Optional) Date of Inspection on which authorisation was granted |
| <input type="checkbox"/> | Annex 5 | (Optional) Additional provisions based on national requirements |

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

hvd medical GmbH

Carl-Zeiss-Str. 30

66740 Saarlouis

1. MEDICINAL PRODUCTS

Medicinal Products for Human Use

Medicinal Products for Veterinary Use

1.1 with a Marketing Authorisation in EEA country(s)

1.2 without a Marketing Authorisation in the EEA and intended for EEA market*

1.3 without a Marketing Authorisation in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

2.5 Other activities(s): (please specify)

3. Medicinal products with additional requirements

3.1 Products according to Art. 83 of 2001/83/EC¹

Products according to Art. 67 of 2001/82/EC

3.1.1 Narcotic or psychotropic products

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.1.4 Radiopharmaceuticals (including radionuclide kits)

3.2 Medicinal gases

3.3 Cold chain products (requiring low temperature handling)

3.4 Other products: (please specify here or make a reference to Annex 5)

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

None.....
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*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

¹ Without prejudice to further authorisations as may be required according to national legislation

ANNEX 3 (Optional)

Name(s) of responsible person(s)

Dr. Frank Ullrich