

“English Translation / Original in German”

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE AND/OR VETERINARY USE: PLEASE NOTE ANNEX 1)

1. Authorisation number / File number
DE_HE_01_WDA_2022_0046 / II 23.1 (Co) 18 L 18.01 - 1562-B
2. Name of authorisation holder
SMS medipool AG
3. Legally registered address of authorisation holder
Robert-Koch-Straße 2a, 66299 Friedrichsthal (ORG-100035887 / LOC-00056811)
4. Address(es) of site(s)
In den Fritzenstücker 9-11, 65549 Limburg a. d. Lahn
Kurhessenstraße 10, 64546 Mörfelden
Hessenring 19-21, 64546 Mörfelden
5. Scope of authorisation
see Annexes 1a, 1b and 1c
6. Legal basis of authorisation
Sect. 52 a Arzneimittelgesetz
(German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorization
Carolin Conradi
8. Signature
On behalf
9. Date
14. December 2022
10. Annexes attached:
☒ Annexes 1a, 1b and 1c Scope of wholesale distribution authorisation

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Authorisation number / File number:

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Name and address of the site:

SMS medipool AG, In den Fritzenstücker 9-11, 65549 Limburg a. d. Lahn

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: none

3. Medicinal products with additional requirements

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

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)

☐ Medicinal products for veterinary use

3.1.5 ☐ Narcotic or psychotropic products

3.1.6 ☐ Medicinal products for food-producing animals

3.1.7 ☐ Prescription medicinal products for veterinary use

3.2 ☐ Medicinal gases

3.3 ☐ Cold chain products (requiring low temperature handling)

3.4 ☐ Other products: none

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

none

*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

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This translation complies with the original document bearing the signature of the competent authority.