Regierung Von Oberbayern

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : DE_BY_04_WDA_2025/ROB-55Ph-2678.Ph_3-527-1-

34

2. Name of Authorisation Holder : Sanomotion GmbH

(ORG-100054388 / LOC-100096311)

: Falkenbach 75, Falkenbach, Freyung, Bavaria, 94078

3. Address(es) of Site(s) : Falkenbach 75, Falkenbach, Freyung, Bavaria, 94078,

Germany **ACTIVE**

: Confidential, Confidential

4. Legally registered address of Authorisation

Holder

5. Scope of authorisation : ANNEX 1

6. Legal basis of authorisation : Art. 77(1) of Directive 2001/83/EC

7. Name of responsible officer of the competent

authority of the member state granting the wholesale distribution authorisation

8. Signature :

9. Date : 2025-02-24

10. Annexes attached : Annex 1 Scope of wholesale distribution authorisation

Annex 2 (Optional) Address(es) of contract wholesale

distribution sites and their authorisation number

Annex 3 (Optional) Name(s) of responsible person(s)

Annex 4 (Optional) Date of Inspection on which

authorisation was granted

Annex 5 (Optional) Additional provisions based on

national requirements

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Sanomotion GmbH (ORG-100054388 / LOC-100096311) , Falkenbach 75, Falkenbach, Freyung, Bavaria, 94078, Germany ACTIVE

Human medicinal products

1. MEDICINAL PRODUCTS

1.1. with a Marketing Authorisation or registration in EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1. Procurement
- 2.3. Supply
- 2.4. Export

Any restrictions or clarifying remarks (for all users): re 1.1: restricted to trade in finished medicinal products that are not subject to mandatory verification (pursuant to Delegated Regulation EU 2016/161) and non-prescription medicinal products

re 2.4: restricted to exports to Hongkong

zu 1.1: beschränkt auf den Handel mit nicht verifizierungspflichtigen (gem. Deligierten Verordnung EU 2016/161) und nicht verschreibungspflichtigen Fertigarzneimitteln

zu 2.4: beschränkt auf die Ausfuhr nach Hongkong



Regierung Von Oberbayern

Certificate No: DE_BY_04_GDP_2025/ROB-55Ph-2678.Ph_3-527-1-34

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Germany confirms the following:

The wholesale distributor (WDA): Sanomotion GmbH

Site address: Falkenbach 75, Falkenbach, Freyung, Bavaria, 94078

OMS Identifiers: (ORG-100054388 / LOC-100096311)

Has been inspected under the national inspection programme in connection with authorisation number DE_BY_04_WDA_2025/ROB-55Ph-2678.Ph_3-527-1-34 in accordance with Art. 77(1) of Directive 2001/83/EC transposed in the following national legislation: Sect. 52a German Medicinal Product Act (wholesale)

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2024-11-28, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2025-02-24

Name and signature of the authorised person of the Competent Authority of Germany

Confidential
Regierung Von Oberbayern
Confidential
Confidential

Details of the authorisation can be found in the Union Database.