

***Finnish Medicines Agency***

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION  
(MEDICINAL PRODUCTS FOR HUMAN USE)**

1. Authorisation Number : FIMEA/2020/004988
2. Name of Authorisation Holder : SAM Nordic Oy
3. Legally registered address of Authorisation Holder : c/o LJR-Accounting, PL 18, Helsinki, FI-00271, Finland
4. Address(es) of Site(s) : Tietokuja 4, Helsinki, FI-00330, Finland
5. Scope of authorisation (complete for each site under 4) : 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 wholesaling authorisation : Confidential, Confidential
8. Signature :
9. Date : 2020-09-22
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:** SAM Nordic Oy, Tietokuja 4, Helsinki, FI-00330, Finland

**1. MEDICINAL PRODUCTS**

- 1.1 with a Marketing Authorisation in EEA country(s)
- 1.2 without a Marketing Authorisation in the EEA and intended for EEA market\*

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

- 2.1 Procurement
- 2.3 Supply

**3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

- 3.1 Products according to Art. 83 of 2001/83/EC \*\*
  - 3.1.2 Medicinal products derived from blood
  - 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.3 Cold chain products(requiring low temperature handling)

**Any restrictions or clarifying remarks (for all users):** Batch specific control of medicinal products derived from blood has to be handled according to Fimea's administrative regulation prior to releasing marketing authorised or special-licence medicinal product to consumption. Supply is limited to radiopharmaceuticals.

\*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

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