

Finnish Medicines Agency

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

1. Authorisation Number : 002818/06.08.00.04/2018
2. Name of Authorisation Holder : Fysioline Oy
3. Legally registered address of Authorisation Holder : Arvionkatu 2, Tampere, 33840, Finland
4. Address(es) of Site(s) : Arvionkatu 2, Tampere, 33840, 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 : 2018-07-02
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: Fysioline Oy, Arvionkatu 2, Tampere, 33840, Finland

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement
2.2 Holding
2.5 Other activities(s): Distribution of medicinal product samples and export of medicinal products to EEA countries

*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

EudraGMDR

Finnish Medicines Agency

Certificate No: 003170/06.08.02.00/2018

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

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

The competent authority of Finland confirms the following:

The wholesale distributor: Fysioline Oy

Site address: Arvionkatu 2, Tampere, 33840, Finland

Has been inspected under the national inspection programme in connection with authorisation number 002818/06.08.00.04/2018 in accordance with Art. 77 (1) of Directive 2001/83/ EC

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2018-05-29, 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.

2018-07-04

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

Confidential

Finnish Medicines Agency

Confidential

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