

National Authority of Medicines and Health Products, I.P.

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

1. Authorisation Number : A023/12/H/003/2021
2. Name of Authorisation Holder : Etiogen, Lda.
3. Legally registered address of Authorisation Holder : Estrada de Paço D' Arcos, n.º 9, Piso 3, Oeiras, 2770-218 Paço de Arcos, Portugal
4. Address(es) of Site(s) : Edifício Logista, Expansão da Área Industrial do Passil, Lote 1 A, Palhavã, Alcochete, 2894-002 Alcochete, Portugal
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 : Maria Fernanda Ralha Henriques Matos, +351 21 7987278
8. Signature :
9. Date : 2021-01-14
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: Etiogen, Lda., Edifício Logista, Expansão da Área Industrial do Passil, Lote 1 A, Palhavã, Alcochete, 2894-002 Alcochete, Portugal

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*
- 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

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
 - 3.1.3 Immunological medicinal products
- 3.3 Cold chain products (requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): National legal basis of authorisation: Art. 94.º of Decree-law 176/2006, of 30th August.

WDA scope activity - Wholesale Distributor.

Updating of the Annex 3 regarding a change of the Responsible Person.

The Authorisation number A023/12/H/003/2021 replaces the previous one with the Authorisation number A023/12/H/002/2016, of 2016-04-18 (Transfer of Facilities).

*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

Anexo 3 / Annex 3

Nome(s) do(s) Director(es) Técnico(s) / Name(s) of Responsible Person(s)

Dr (a). Cátia Sofia Felício Caetano