

CERTIFICADO N.º

À presente data certifica-se que TILIAFARM - COMERCIALIZAÇÃO DE PRODUTOS FARMACÊUTICOS, LDA, NIPC 508891140 notificou o Infarmed – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P no âmbito do exercício das atividades de Distribuição de dispositivos médicos, nos seguintes termos:

Sede: Rua Joaquim Paço D'Arcos, nº 11, 1500-365, Lisboa

Instalação: Rua Quinta dos Grilos, n.º 30, Piso -1 e Piso 0, Oeiras

2790-476

Carnaxide

Responsável Técnico(a): Zhara Badrudin Ekbal

Atividade: Distribuição

Lisboa, 01 de Agosto de 2023

DIREÇÃO DE INSPEÇÃO E LICENCIAMENTOS
UNIDADE DE LICENCIAMENTOS

National Authority Of Medicines And Health Products

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

- | | | |
|--|---|---|
| 1. Authorisation Number | : | <div></div> |
| 2. Name of Authorisation Holder | : | Tiliafarm Comercializacao De Produtos Farmaceuticos Lda.

(ORG-100013397 / LOC-100018767) |
| 3. Legally registered address of Authorisation Holder | : | Rua Joaquim Paco D'arcos No 11, Lisbon, 1500-365 |
| 4. Address(es) of Site(s) | : | Rua Quinta Dos Grilos 30 Piso 1 E Piso 0, Carnaxide, 2790-476, 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
National legal basis of authorisation: Art. 94.º of Decree-law 176/2006, of 30th August. |
| 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 | : | <div><div>Maria
Fernanda
Ralha</div><div></div></div> |
| 9. Date | : | 2024-05-17 |
| 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: Tiliafarm Comercializacao De Produtos Farmaceuticos Lda.
(ORG-100013397 / LOC-100030697)
, Rua Quinta Dos Grilos 30 Piso 1 E Piso 0, Carnaxide, 2790-476, Portugal

Human medicinal products

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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.3 Cold chain products(requiring low temperature handling)
- 3.4 Other products: Homeopathic, Immunomodulators, Biological, Cytotoxic and Cytostatic medicinal products.

Any restrictions or clarifying remarks (for all users): WDA scope activity - Wholesale Distributor.

Complete Site Address: Rua Quinta dos Grilos, n.º 30, Piso -1 e Piso 0 - 2790-476 Carnaxide

Updating of the Annex 1 regarding the inclusion of the medicinal products derived from blood; Immunological, Immunomodulators, Biological, Cytotoxic and Cytostatic medicinal products.

*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). Zhara Badrudin Ekbal