

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

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

- | | |
|--|---|
| 1. Authorisation Number | : A010/14/H/006/2021 |
| 2. Name of Authorisation Holder | : Odisseiamargem - Produtos Farmacêuticos, Lda. |
| 3. Legally registered address of Authorisation Holder | : Rua Arnaldo Gama, Lote 3514 A, Pinhal de Frades, Seixal, 2840-301 Seixal, Portugal |
| 4. Address(es) of Site(s) | : Rua Arnaldo Gama, Lote 3514 A, Pinhal de Frades, Seixal, 2840-301 Seixal, 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 | : 2021-06-21 |
| 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: Odisseiamargem - Produtos Farmacêuticos, Lda., Rua Arnaldo Gama, Lote 3514 A, Pinhal de Frades, Seixal, 2840-301 Seixal, Portugal

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1 Products according to Art. 83 of 2001/83/EC **
 - 3.1.1 Narcotic or psychotropic products
 - 3.1.2 Medicinal products derived from blood
- 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 1 regarding the inclusion of the Narcotic or Psychotropic products.

The Authorisation number A010/14/H/006/2021 replaces the previous one with the Authorisation number A010/14/H/005/2021, of 2021-01-05.

*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). Maria Helena Barros Tavares