

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

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

1. Authorisation Number : A028/14/H/002/2017
2. Name of Authorisation Holder : Bluemed, Unipessoal, Lda.
3. Legally registered address of Authorisation Holder : Rua Poeta Adriano Correia de Oliveira, n.º 233, Gondomar, 4510-698 Fânzeres, Portugal
4. Address(es) of Site(s) : Rua do Rio, n.º 32, Maia, 4475-493 Maia, 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 : 2017-05-11
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:** Bluemed, Unipessoal, Lda., Rua do Rio, n.º 32, Maia, 4475-493 Maia, 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 \*\*
  - 3.1.1 Narcotic or psychotropic products
  - 3.1.2 Medicinal products derived from blood
  - 3.1.3 Immunological medicinal products
  - 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.2 Medicinal gases
- 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.

3.2 Medicinal gases – They aren't stored in the facilities of this Wholesale distributor; they go directly from the manufacturer to the Wholesale distributor customers.

The Authorisation number A028/14/H/002/2017 replaces the previous one with the Authorisation number A028/H/001/2014, of 2014-04-03. (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