

**GRACOPA BV : VERGUNNING GMDP n° 1567 H**

Bij toepassing van de artikels 12bis en 12ter van de wet van 25 maart 1964 op de geneesmiddelen:

de firma : **Gracopa BV**

ondernemingsnummer 0479.314.810  
maatschappelijke zetel Antoine Dansaertstraat 108  
1000 Brussel  
administratieve zetel Langestraat 151  
3111 Wezemaal

met als plaats van verrichtingen :

- Langestraat 151, 3111 Wezemaal
- Auxi-Export SRL, Excelsiorlaan 16, 1930 Zaventem  
(activiteiten beperkt tot opslag in loondienst)

wordt vergunning verleend om:

- de activiteiten uit te voeren aangegeven op de vergunning voor distributie (WDA)  
(2 pagina's)



Voor de minister van Volksgezondheid,  
de administrateur generaal,  
Xavier De Cuyper

In opdracht Philippe De Buck  
DG Inspectie – Diensthoofd Afdeling Vergunningen

***Federal Agency for Medicines and Health Products***

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

1. Authorisation Number : 1567 H
2. Name of Authorisation Holder : Gracopa BV
3. Legally registered address of Authorisation Holder : Antoine Dansaertstraat 108, Brussel, 1000, Belgium
4. Address(es) of Site(s) : Langestraat 151, Wezemaal, 3111, Belgium
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 : Xavier De Cuyper, +32 2 5284000
8. Signature :
9. Date : 2021-09-28
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:** Gracopa BV, Langestraat 151, Wezemaal, 3111, Belgium

**1. MEDICINAL PRODUCTS**

1.1 with a Marketing Authorisation in EEA country(s)

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

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

3.1.3 Immunological medicinal products

3.3 Cold chain products(requiring low temperature handling)

**Any restrictions or clarifying remarks (for all users):** 3.3.: Authorized temperature for the cold chain : 2-8°C

3.3.: Toegestane temperatuur voor de koude bewaring : 2-8°C

\*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