

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 0952
2. Name of authorisation holder Profarma UAB (ORG-100024953 / LOC-100034143)
3. Address(es) of manufacturing site(s) Profarma UAB (ORG-100024953 / LOC-100054473), V. A. Graiciuno G. 6, Vilniaus M. Sav., Vilnius, 02241, Lithuania
4. Legally registered address of authorisation holder V. A. Graiciuno G. 8, Vilniaus M. Sav., Vilnius, 02241, Lithuania
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2022-10-19
10. Annexes attached
Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3(Addresses of Contract Manufacturing Site(s))
Annex 4(Addresses of Contract laboratories)
Annex 5(Name of Qualified Person)
Annex 6(Name of responsible persons)
Annex 7(Date of inspection on which authorisation granted, scope of last inspection)
Annex 8(Manufactured/ imported products authorised)³

¹The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Profarma UAB, V. A. Graiciuno G. 6, Vilniaus M. Sav., Vilnius, 02241, Lithuania

Additional Details:

Human Medicinal Products

Authorised Operations IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.2 Microbiological: non-sterility</i>
	<i>2.1.3 Chemical/Physical</i>
	<i>2.1.4 Biological</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i>
	2.2.1.1 Aseptically prepared

Any restrictions or clarifying remarks related to the scope of these Importation operations (for Public users)

Legal/Headquarters address: Vilniaus m. sav., Vilniaus m., V.A. Graičiūno g. 8B, LT-02241, Lithuania
The address of activity site: Vilniaus m. sav., Vilniaus m., V.A. Graičiūno g. 6-2, LT-02241, Lithuania