

GMP Compliance Menu

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Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Lithuania confirms the following:

The manufacturer: **Profarma, UAB**

Site address: **V.A. Graičiūno g. 6, Vilnius, LT-02241, Lithuania**

Other

(Human) Buvo patikrinta kaip kokybės kontrolės laboratorija, atliekanti tyrimus pagal sutartį gamybos įmonėms, turinčioms gamybos licencijas išduotas pagal Direktyvos 2001/83/EB 40 straipsnį, perkeltą į LR farmacijos įstatymą 2006-06-22 / Has been inspected in connection with manufacturing authorisation where the company is listed as a site of QC testing, in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: Law on Pharmacy 22 June 2006, No X-709.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-10-23**, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC ⁽³⁾

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

⁽¹⁾ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

⁽²⁾ Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

⁽³⁾ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS**1.6 Quality control testing**

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical

2019-12-05

Name and signature of the authorised person of the Competent Authority of Lithuania

Confidential**State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania**Tel: **Confidential**Fax: **Confidential**

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Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on [EMA's website](#)