EudraGMDP

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State Medicines Control Agency

CERTIFICATE NUMBER:***LT08H/2019***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1) , (2)*

Part 1

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, perkelta į: LR farmacijos įstatymą 2006-06-22 / Has been inspected in connection with manufacturing authorisationwhere the company is lis listing 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/ECis 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***