



Crna Gora
Montenegro



Sertifikat broj: 2050/24/493/2-8431

Certificate No: 2050/24/493/2-8431

SERTIFIKAT O USAGLAŠENOSTI VELEDROGERIJE SA GDP SMJERNICAMA
(GDP SERTIFIKAT – LJEKOVI ZA HUMANU UPOTREBU)
CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR
(GDP CERTIFICATE – MEDICINES FOR HUMAN USE)

Izdaje se na osnovu člana 142 st. 3 i 4 Zakona o lijekovima ("Službeni list CG", br. 80/20 i 84/24) nakon sprovođenja inspekcije (član 111 Direktive 2001/83/EC).

Issued in accordance with Article 142 paragraphs 3 and 4 of the Law on medicines ("Official Gazette of Montenegro", No. 80/20 and 84/24) following an inspection (Article 111 of Directive 2001/83/EC).

Institut za lijekove i medicinska sredstva potvrđuje sljedeće:

Institute of Medicines and Medical Devices confirms the following:

Veledrogerija

The wholesale distributor

Nelt MNE DOO

Nelt MNE LLC

Adresa mjesta inspekcije

Site address

Bulevar 21. maj 140, Podgorica, Crna Gora

Bulevar 21. maj 140, Podgorica, Montenegro

je inspektovana u skladu sa nacionalnim programom inspekcije u vezi sa dozvolom za promet lijekova na veliko broj 2050/23/529/3-7549 od 27.10.2023. godine u skladu sa članom 77 stav 1 Direktive 2001/83/EC koji je transponovan u sljedeći nacionalni propis: Član 133 stav 4 Zakona o lijekovima.
has been inspected under the national inspection programme in connection with wholesale authorisation number 2050/23/529/3-7549 issued on 27/10/2023 in accordance with Article 77 (1) of Directive 2001/83/EC transposed in the following national legislation: Article 133 paragraph 4 of the Law on medicines.

Na osnovu saznanja stečenih tokom inspekcije ove veleadrogerije, koja je posljednji put sprovedena 10.11.2023. godine, smatra se da je usaglašena sa zahtjevima smjernica Dobre prakse u distribuciji u skladu sa članom 84 Direktive 2001/83/EC koji je transponovan članom 139 stav 8 Zakona o lijekovima.

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 10/11/2023, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC transposed in the Article 139 paragraph 8 of the Law on medicines.

Ovaj GDP sertifikat je sastavni dio rješenja Instituta za lijekove i medicinska sredstva broj 2050/24/493/2-8431 od 12.11.2024. godine.
This GDP certificate is a part of the decision of the Institute for Medicines and Medical Devices class 2050/24/493/2-8431 issued on 12/11/2024.

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T: + 382 (0) 20 310 280 / + 382 (0) 20 310 281 / + 382 (0) 20 310 580

M: info@cinmed.me W: www.cinmed.me A: Bulevar Ivana Crnojevića 64a, 81000 Podgorica, Crna Gora

PIB: 02739658 ŽR: 520-3603-33 - Hipotekarna Banka / 530-166587-93 - NLB Banka



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Ovaj sertifikat odražava stanje naprijed navedenih prostorija u vrijeme inspekcije i ne može se smatrati da odražava status usaglašenosti ako je proteklo više od pet godina od datuma predmetne inspekcije. Međutim, taj rok važnosti može da se smanji primjenom regulatornih načela upravljanja rizikom unosom u polje Ograničenja ili Pojašnjenja.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However, this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

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The authenticity of this certificate may be verified on the web page of the Institute. If it does not appear please contact the issuing authority.

Sva ograničenja ili pojašnjenja u vezi sa područjem primjene ovog sertifikata: GDP sertifikat važi do 10.11.2026. godine.

Any restrictions or clarifying remarks related to the scope of this certificate: The certificate is valid until 10/11/2026.

12.11.2024. godine

12th November 2024

Ime, prezime i potpis ovlašćenog lica
Instituta za lijekove i medicinska sredstva
*Name and signature of the authorised person of
the Institute for Medicines and Medical Device*

DIREKTOR

Managing Director

Snežana Mugoša, MD, MSc, PhD, spec



Detaljni podaci o dozvoli za promet na veliko dostupni su na internet stranici Instituta.

Details of the authorisation can be found on the web page of the Institute.

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