State Institute for Drug Control

Certificate No: sukls29281/2023

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Czechia confirms the following:

The wholesale distributor (WDA): Pharma Solutions s.r.o.

Site address: Karasek 1, Reckovice, Brno, 621 00

OMS Identifiers: (ORG-100004298 / LOC-100006079)

Has been inspected under the national inspection programme in connection with authorisation number sukls287609/2018 in accordance with Art. 77 (1) of Directive 2001/83/ EC transposed in the following national legislation: Section 101 paragraph 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2022-04-26, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

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.

This certificate is valid only when presented with all pages.

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

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users): warehouse is in Areál Biovedor a.s. - Laboratorní medicína obj. č. 4

2023-02-13

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