

*Agency for medicinal products and medical devices of the Republic of
Slovenia*

Certificate No: 455-2/2021-1

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

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

The competent authority of Slovenia confirms the following:

The wholesale distributor: ISTRABENZ PLINI, plini in plinske tehnologije, d.o.o.

Site address: Sermin 8A, Koper, 6000, Slovenia

Has been inspected under the national inspection programme in connection with authorisation number 801-2/2021-6 in accordance with Art. 77 (1) of Directive 2001/83/ EC

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2019-07-11, 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):

The certificate is valid for wholesale distribution activity for a restricted scope of medicinal products that only covers the wholesale distribution of specified medicinal products, in line with the remark on the corresponding WDA.

2021-02-03

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



Mr Jaka Zavasnik

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Republic of Slovenia

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Details of the authorisation can be found in the Union Database.

