



ISF.405.112.2024.IP.4
WTC/0047_02_02/205

**CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES
FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE**

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

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the active substance importer

**Farmaceutyczna Spółdzielnia Pracy „GALENA”
ul. Dożynkowa 10, 52-311 Wrocław, POLAND**

site address

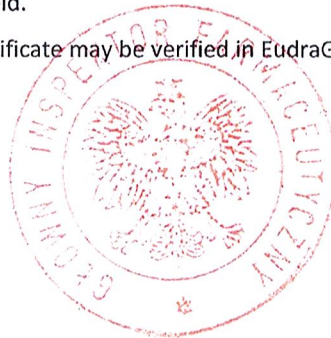
**Farmaceutyczna Spółdzielnia Pracy „GALENA”
ul. Dożynkowa 10, 52-311 Wrocław, POLAND**

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686) and in connection with registration no **29/WTC0047/API/15**.

From the knowledge gained during inspection of this active substance importer, the latest of which was conducted on **28/06/2024** it is considered that it complies with the principles of good distribution practice for active substances referred to in article 47 of Directive 2001/83/EC.

This certificate reflects the status of the site 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.

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



Chief Pharmaceutical Inspector

Lukasz Pietrzak
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