

PERMIT

According to art. 38 st. 1 and 2 statutes from 6 Sept., 2001 – Pharmaceutical law (Dz.U. from 2004, no. 53 pos. 533 with further changes)

after considering the application on changing the permission for the manufacturing and processing of healthcare products nr. GIF-IW-4000/48/04 from 18 Oct., 2004

I grant permission for the manufacturing and processing of healthcare products to

KATO LABS Sp. z o.o.

ul. Marszałkowska 138/82, 00-004 Warsaw

KRS Company Registry no.: 0000100735

1. Permit includes:

1. Non-steril products

1.1 Liquid form

1.2 Semisolid form

1.3 Solid form

1.3.1 Single-dose

2. Packaging or repackaging

2.1 Liquid form

2.2 Semisolid form

2.3 Solid form

2.3.1 Into direct package

2.3.2 Into outer package

3. Products for clinical research

2. Place of manufacture:

Kato Labs Sp. z o.o. Pharmaceutical Manufacturer

Product Manufacturing and Distribution Center

ul. Instalatorów 9, 02-239 Warsaw

3. Place of Control:

Kato Labs Sp. z o. o. Pharmaceutical Manufacturer

Product Manufacturing and Distribution Center

ul. Instalatorów 9, 02-239 Warsaw

4. Name of the healthcare product: attachment

JUSTIFICATION:

According to art. 107 st. 4 from the statute book of administrative proceedings, justification was withdrawn since the decision was taken into account in full on request of the party.

Information:

According to art. 127 st. 3 from the statute book of administrative proceedings, the side may proceed to the Head Pharmaceutical Inspector with an application to reconsider this matter within the term of 14 days from the day of receiving the above decision.

GIF seal
signed Zofia Ulz

Received:

1) Kato Labs Sp. z o.o.

ul. Marszałkowska 138/82, 00-004 Warsaw

2) Appropriate Manufacturing Inspector

3) a/a.