

(Crest)

MINISTRY OF HEALTH

No.: 515-04-02435/2014-11

Date: 11 June 2014

Belgrade, Nemanjina no. 22-26

Tel. 011/311-4949

ZN

The Ministry of Health of the Republic of Serbia, acting upon the application of **Trgovinsko preduzeće SB TRADE d.o.o. Beograd** (Trade Company SB TRADE Ltd. Belgrade), **Bitoljska no. 20**, for change of permit for wholesale trade in medicines and medical devices, and pursuant to Article 212, Par. 6 of the Law on Medicines and Medical Devices (Official Gazette RS no. 30/2010 and 107/2012) and Article 192, Par. 1, Item 1 of the Law on General Administrative Procedure (Official Bulletin FRY nos. 33/97 and 31/2001), enacts the following

DECISION

I A PERMIT IS HEREBY ISSUED to Trgovinsko preduzeće SB TRADE d.o.o. Beograd, Bitoljska no. 20 for wholesale trade – import, export, procurement, storage, and distribution in the territory of the Republic of Serbia from commercial warehouses with a total area of 140.21 sqm in Belgrade, Kružni put no. 26, of the following:

1. **Human medicines** according to the ATC (Anatomical Therapeutic Chemical) Classification, the following main therapeutic groups:
 - D08 - Antiseptics and disinfectants
2. **Traditional medicines**
3. **Medical devices**
 - Class IIa
 - Category 10 – Disposable medical devices
4. **Starting substances for manufacture, i.e. production of galenic and magistral drugs in manufacturer's original packaging.**

II Ministry of Health Decision no. 515-04-05375/2011-08 of 30 November 2011 IS HEREBY CANCELLED.

Explanation

Trgovinsko preduzeće SB TRADE d.o.o. Beograd, Bitoljska no. 20 submitted, on 15 May 2014, a petition for change of permit for wholesale trade in medicines and medical devices no. 515-04-05375/2011-08 of 30 November 2011, whereby they would trade in medicines according to the ATC classification and this only for the main therapeutic group D08, traditional medicines, medical devices of Class IIa Category 10, and starting substances for manufacture, i.e. production of galenic and magistral drugs in the manufacturer's original packaging, from the warehouse located at the same address Belgrade, Kružni put no. 26.



Acting upon the said application and pursuant to Article 208, Par. 3, Item 2, the Inspector for Medicines and Medical Devices, inspected the facilities and equipment for storage and safekeeping of medicines and medical devices, the means of transport, and compliance with terms regarding staff qualifications as set forth in the Inspector's Minutes no. 515-04-02435/2014-11 of 10 June 2014.

Based on the verified factual situation and the submitted documentation compliance was confirmed with the requirements for operating wholesale trade in medicines and medical devices set forth in the introductory part of this Decision, in accordance with Articles 120 -123, 193, 194 of the Law on Medicines and Medical Devices (Official Gazette RS, no. 30/10 and 107/2012) and Articles 3, 10, 11, 13, 15, 21, 22, and 30 of the Rules on the Terms for Wholesale Trade in Medicines and Medical Devices, the data entered in the Register of Issued Permits for Wholesale Trade in Medicines and Medical Devices, and the Manner of Registration (Official Gazette RS no. 10/12).

Since Trgovinsko preduzeće SB TRADE d.o.o. Beograd, Bitoljska no. 20 possesses Ministry of Health Decision No.: 515-04-05375/2011-08 of 30 November 2011 for warehousing at the same address, the amendment of which they have requested under the decision, the issue of this Decision renders the said decision null and void.

Based on the above the Decision was made as set forth above.

This Decision is final in administrative procedure.

This Decision may be disputed by taking administrative action before the competent court within 30 (thirty) days of receipt hereof.

A fee for this Decision was charged on the basis of the Law on State Administration Fees (Official Gazette RS no. 47/13).

Cc:

- SB TRADE d.o.o. Beograd, Bitoljska no. 20
- Archive
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THE MINISTER
(Signature)
Acc. Dr. Zlatibor Lončar

5153014.0038.149/2/JJ

END OF TRANSLATION

I hereby certify that this is a true and correct translation into English of the original made out in the Serbian language. In testimony thereof I affix hereunto my signature and seal of office.

Belgrade, 07 February 2019
Cert. 63/2019

Vesna Kordić-Lazić
Sworn Court Interpreter for the English Language
License No. 740-02-00059/93-01 of 03 June 1993 issued by
the Ministry of Justice of the Republic of Serbia
Address: Vojislava Ilića 25, 11050 Belgrade, Serbia
Mob: +381 65 6311260
E-mail: vesnakordiclazic@gmail.com

Vesna Kordić-Lazić

