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Riga

No. 7-2/1862 of 04.11.2019
To No. without number of 15.10.2019

LLC "Healthcare Products and Technologies"
Reg. No. 40203185831
17-64 Salacas Street, Riga, LV-1019

Regarding Examination of the Information
Provided by the Manufacturer of Medical Devices
and Its Inclusion in Databases

On October 16, 2019 the State Agency of Medicines (hereinafter – SAM) received the application of LLC "Healthcare Products and Technologies" (hereinafter – Applicant) dated October 15, 2019, requesting to register the Applicant as a manufacturer of non-sterile class I medical devices without measuring function indicated in the application.

Pursuant to Articles 117 and 120 of the Regulation No. 689 adopted by the Cabinet of Ministers on November 28, 2017 *Procedure for Registration, Assessment, Distribution, Exploitation and Technical Supervision of Medical Devices* (hereinafter – Regulation No. 689), and Article 2 of the Decision 2010/227/EU made by the European Commission on April 19, 2010 regarding the European databank of medical devices (*Eudamed*), the Agency has examined the application of the Applicant dated October 15, 2019 and entered the following information in the electronic database of the Register of Medical Devices LATMED and the European Databank of Medical Devices *Eudamed*,

1. Manufacturer of medical devices: Limited Liability Company "Healthcare Products and Technologies" (registration No. 40203185831, legal address: 17-64 Salacas Street, Riga, LV-1019);
2. LLC "Healthcare Products and Technologies" produces the following non-sterile class I medical devices without measuring function:
   - Medical device HEAD BANDAGE / BANDANA FILLED WITH MICROSPHERES,
   - Medical device BOOTS / SLIPPERS FILLED WITH MICROSPHERES,
   - Medical device BACK BANDAGE / VEST FILLED WITH MICROSPHERES,
   - Medical device SLEEPING MASK FILLED WITH MICROSPHERES,
   - Medical device HAND MUFF FILLED WITH MICROSPHERES,
   - Medical device BELT BANDAGE FILLED WITH MICROSPHERES,

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- Medical device HIGH SLIPPERS FILLED WITH MICROSPHERES,
- Medical device TRAPPER HAT FILLED WITH MICROSPHERES.

Please be reminded that in view of the requirements of Articles 118 and 120 of the Regulation No. 689, a manufacturer of medical devices is obliged to inform the Agency of changes in the provided information, as well as of termination of production of medical devices within 10 working days after the relevant changes have taken place.

Acting Director - Deputy Director Janis Zvejnieks

The document is signed with a secure electronic signature and contains a timestamp.

Andis Vilums
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2019/20467

TRUE COPY
Riga, November 5, 2019

/seal: Republic of Latvia
State Agency of Medicines/

Administrative Department
Administrator
Sandra Bedike
/signature/