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Riga

No. 7-2/316 28.02.2019
To No. without number of 18.02.2019

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

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

On February 20, 2019 the State Agency of Medicines (hereinafter – SAM) received the application of LLC "Healthcare Products and Technologies" dated February 18, 2019, requesting to register LLC "Healthcare Products and Technologies" as a manufacturer of medical devices.

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 on medical devices (*Eudamed*), the Agency has examined the application of LLC "Healthcare Products and Technologies" dated February 18, 2019 and entered the following information in the electronic database of the Register of Medical Devices LATMED and the European Databank on 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 and releases onto the market the following 1st class medical devices:
   - Medical device VARIFORT R anti-varicose and joint anesthetic bandage (sizes X, S, S1, M, M1, L, L1, L2, L3),
   - Medical device UNIVERSAL APPLICATOR (sizes 38x45 cm),
   - Anatomic mattress filled with microspheres (sizes 60x120 cm, 70x100 cm, 80x180 cm, 80x200 cm, 90x200 cm, 150x200 cm, 160x200 cm, 180x200 cm, 200x200 cm),
   - Anatomic pillow filled with microspheres (sizes in accordance with the EU declaration of conformity).

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

Director /*signature*/ Svens Henkuzens

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

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