

Number: 310-56/2013-4

Date: 04.11.2013

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ptujška ulica 21, 1000 Ljubljana, on the basis of Articles 49 and 50 of the Medical Devices Act (Official Gazette of RS, no. 98/09) and 22 and 23 of the Rules of medicinal products (Official Gazette of RS No. 37/2010 and 66/2012) and the application for entrance into the medical devices by Ham, Production of SpinaliS chairs, d.o.o., Gerbičeva ulica 102, 1000 Ljubljana, Slovenia, No. 310-56/2013 dated 11.09.2013 issues the following

## DECISION

1. The medical devices register shall enter the medical device of the producer HAM, production of SpinaliS chairs, d.o.o., Gerbičeva ulica 102, 1000 Ljubljana, Slovenia as follows:

Generic name: Therapeutic chair for active sitting

Classification: grade 1

Store name	Model
SpinaliS	Smart, Ergonomic, Basic, Hacker, Apollo, Navigator, Spider, Pilot, Dent, Stylist, Rodeo

2. This Decision shall apply until the date of expiry of the EC declaration of conformity.
3. The fee for the registration of medical devices in accordance with 09 Article of fee and medical devices (Official Gazette of RS, no. 37/2010) for an application and the issuance of this Decision in the amount of EUR 100 is paid

Reason:

HAM, production of SpinaliS chairs, d.o.o., Gerbičeva Ulica 12, 1000 Ljubljana, Slovenia (hereinafter referred to as the applicant) is in accordance to 45, 49, 50 Article of Medical Devices Act (Official Gazette of RS, no. 98/09, hereinafter referred to as the Act) and 22, 23 articles of Medicinal products (Official Gazette of RS, no. 37/2010 and 66/2012; hereinafter referred to as the Rules), filed on 09/11/2013 at the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter referred to as JAZMP) an application of entry of a medical device, as shown in the disposition, in the register of

medical devices, application number 310-56/2013

JAZMP concluded that the application was not complete, so the applicant on 10.10.2013 was issued a request for amendment to the application no. 310-56/2013-2, stating the shortcomings of the application. On 25.10.2013 the applicant successfully fulfilled the request.

After finding that the application, taking into account Article 50 of the Act and paragraph 23 of the Rules was complete on the date 10.25.2013, JAZMP issued the decision which is justified.

The decision shall be issued in duplicate. One copy shall go to the applicant and the other remains in the archive of JAZMP.

Legal Warning:

Such a decision may be appealed to the Ministry of Health, Štefanova 5, 1000 Ljubljana, within 15 days from the date of notification of the decision. An appeal must be lodged in writing or orally on the record at the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ptujška 21, 1000 Ljubljana. The administrative fee for appeal under heading 2 of the Administrative Fees Act (Official Gazette of RS, no. 42/2007, 126/07 and 88/2010), in the amount EUR 18.12 is to be paid to the budget of the Republic of Slovenia no. 01100-1000315637, reference 11 27650-7111002. An appeal must accompany by a copy of this decision.

Process led by:

Tamara Odar. Univ. graduate microbiologist

MSc. Igor Lipušček, Univ. graduate engineer



By mandate of:  
Dr. Matej Breznik. Mag. Pharmacy  
Director

