

Czech National Emblem
STATE INSTITUTE

Šrobárova 48

Telephone: +420 272 185
111

E-mail:
posta@sukl.cz

FOR DRUG CONTROL

100 41 Praha 10

Fax: +420 271 732 377

Web:
www.sukl.cz

TO
EUROPE IVF International s.r.o.
Nad Výšinkou 2868/2
150 00 Prague 5 – Smíchov

File No.
sukls198920/2016
Reg. No.:
sukl201110/2016

Person responsible/extension:
Tomková/742

Date
08/08/2016

DECISION

The State Institute for Drug Control, with registered office in Prague 10, Šrobárova 48, as the body competent to issue decisions pursuant to Section 15(1), Letter a) of Act No. 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended, (hereinafter only the "Act on Human Tissues and Cells") hereby decided in accordance with the provision of Section 67 of Act No. 500/2004 Coll., Rules of Administrative Procedure, as amended (hereinafter only the "Rules of Administrative Procedure")

as follows:

The State Institute for Drug Control (hereinafter only the "Institute"), in accordance with Section 20(1) of Act No. 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended, (hereinafter only the "Act on Human Tissues and Cells") hereby changes the permission of activity of the tissue establishment issued on 26/02/2016 under File No. sukls48593/2016 as follows:

- Another activity of the entity performing the activities assigned based on a contract pursuant to Section 10 of the Act on Human Tissues and Cells is registered, i.e. the contractual diagnostic laboratory, SPADIA LAB, a.s., with registered office at Rožnovská 241, 744 01 Frenštát pod Radhoštěm, Company ID No.: 28574907 (laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 5, Points 3.3. and 3.7.).

The current scope of the permission of activity of a tissue establishment including all the changes (Decision, File No. sukls48593/2016 dated 26/02/2016, Decision, File No. sukls50678/2012 dated 26/03/2012 and Decision, File No. sukls69932/2011 dated 26/07/2011 together with the change above is as follows:

EUROPE IVF International s.r.o. with registered office at Nad Výšinkou 2868/2, 150 00 Prague 5 – Smíchov, Company ID No.: 24684287 is permitted the activity of a

tissue establishment

for the types of tissues and cells and scope of activities:

Sperm, oocytes, embryos, testicular/epididymal tissue	
For the use between the partners and non-partner donation	
In the scope of activities performed	Collection, processing, examination, release, storage, distribution

In accordance with Section 19(2) of the Act on Human Tissues and Cells, the Institute imposes the obligation to observe the conditions under which this permission of activity was issued to the holder of this permission of the activity, namely:

a) The function of a person responsible of the tissue establishment is performed by	MUDr. David Kult RNDr. Eva Cibulková Mgr. Monika Pichlerová Ing. Vilma Lánská, Ph.D.
b) Addresses of all the places where the activities are performed are	Nad Výšinkou 2868/2, 150 00 Prague 5 – Smíchov
c) Activities assigned based on a contract pursuant to Section 10 of the Act on Human Tissues and Cells	- AeskuLab a.s., with registered office at Evropská 2589/33b, 160 00 Prague 6, Company ID No.: 60470488 (laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 4, Point 1.1. and Annex No. 5, Point 3.3.); - GENvia, s.r.o., with registered office at Karlovo náměstí 325/7, 120 00 Prague 2, Nové Město (genetic laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 5, Point 3.7.); - Česká laboratorní s.r.o., with registered office at Antala Staška 1859/34, Krč, 140 00 Prague 4, Company ID No.: 03888592 (laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 4, Point 1.1.); - SPADIA LAB, a.s., with registered office at Rožnovská 241, 744 01 Frenštát pod Radhoštěm, Company ID No.: 28574907 (laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 4, Point 1.1. and Annex No. 5, Points 3.3. and 3.7.)

Grounds:

As of 02/08/2016, EUROPE IVF International s.r.o. with registered office at Nad Výšinkou 2868/2, 150 00 Prague 5 – Smíchov, Company ID No. 24684287, filed the application on the change of permission of activity of a tissue establishment issued on 26/02/2016 under File No sukls48593/2016. The change is represented by the registration of another activity of the entity performing activities assigned based on a contract pursuant to Section 10 of the Act on Human Tissues and Cells, i.e. the contractual diagnostic laboratory, SPADIA LAB, a.s., with registered office at Rožnovská 241, 744 01 Frenštát pod Radhoštěm, Company ID No.: 28574907 (laboratory examination of donors pursuant to Decree No. 422/2008 Coll., Annex No. 5, Points 3.3. and 3.7.). By filing this application, the administrative proceeding was opened, under File No. sukls198920/2016. Within the proceeding, the Institute considered whether the requirements stipulated by the Act on Human Tissues and Cells and its implementing regulations have been met in the given case in the scope of activities performed and for the types of tissues and cells as specified in the statement of this Decision.

At the same time, in accordance with Section 19(2) of the Act on Human Tissues and Cells, the Institute imposes the obligation to observe the conditions under which this permission of activity was issued to the holder of this permission of the activity. The Institute states the details decisive for the issue of the permission (persons responsible of the tissue establishment, place of performance of activities and contractual activities which the tissue establishment may assign pursuant to Section 10 of the Act on Human Tissues and Cells) – i.e. the facts whose failure to observe them would constitute a change against the conditions under which this permission for the given type of tissues and cells and the scope of activities has been issued as these are the facts which might affect the quality and safety of the given type of tissues and cells.

(Certified Translation from Czech)

Taking this into account, the Institute decided on the change in the permission of activity as specified in the statement of this Decision.

The other part of the statement contains the scope of the permission of activity of a tissue establishment, as amended (Decision, File No. sukls48593/2016 dated 26/02/2016, Decision, File No. sukls50678/2012 dated 26/03/2012 and Decision, File No. sukls69932/2011 dated 26/07/2011).

Advice

Appeal may be filed against this Decision, pursuant to the provisions of Section 81 *et seq.* of the Rules of Administrative Procedure at the Institute, **within 15 days** of the day of delivery hereof. The appeal shall be decided by the Ministry of Health of the Czech Republic.

imprint of the official stamp

Ing. František Chuchma, CSc.
Inspection Department Head

TLUMOČNICKÁ DOLOŽKA

Já, Mgr. Kateřina Danielová, jako tlumočnice jazyka českého a anglického ustanovená dekretem Krajského soudu v Brně, ze dne 21. května 2001, č.j. Spr 3483/2000, stvrzuji, že mnou provedený překlad souhlasí s textem připojené listiny.

Tlumočnický úkon je zapsán v deníku pod poř. č.

V Rudici, dne



CERTIFIED TRANSLATION

I, Mgr. Kateřina Danielová, Czech-English/English-Czech translator, appointed by Decree of Regional Court in Brno, Reg. No. Spr 3483/2000, dated 21 May 2001, hereby certify that the translation performed by me is a true translation of the wording of the instrument attached.

The translation is recorded in the Translator's records under Reg. No. 5319/2014

In Rudice, on 12. 04. 2014

