



**CG** *The Ministry of Health, Welfare and Sport*

➤ Return address PO Box 16114 2500 BC The Hague

Cryo-Save Foundation  
Mr. M.J. Waeterschoot, pharmacist  
IJsselkade 8  
7201 HB ZUTPHEN

**Unit Farmatec-BMC**  
Visiting address  
Wijnhaven 16  
2511 GA The Hague

T 070 340 75 00  
F 070 340 74 26  
www.farmatec.nl  
info@farmatec.nl

**Information from:**  
Mr. R. Ramdayal  
070 - 340 5947

**Our reference:**  
Farmatec-BMC/JZ-9659

**Appendices**

**Your letter:** 6 February 2009

Date: 28 April 2010  
Subject: Complying with an application  
Application number: 9659

The CIBG is an executive organization of the  
Ministry of Health, Welfare and Sport

Send correspondence solely to the return address,  
stating the date and the reference of this letter

Dear Mr. Waeterschoot,

The Cryo-Save Foundation has been recognized as an organ bank, with register number 108153 L/EO\*, on account of the Law for Safety and Quality of Human Material (Wvkl).

In the letter of 10 February 2009 I confirmed the receipt of your letter, dated 6 February 2009 (reference: SCS/20090206), to change the recognition as an organ bank and stated to you that your application for advice was submitted to the Health Inspectorate (IGZ). Furthermore, I also submitted your letters, dated 13 October 2009 (reference: SCS/20091013) and 15 December 2009 (reference: SCS/20091215), for advice to IGZ.

In a letter of 29 March 2010 (reference: 2010-228994/Pr8/AvS/rf), which I received on 30 March 2010, IGZ advised me about your application. The advice shows that you meet the requirements in question. I established that the advice has been effected in a careful way.

The above-mentioned recognition had already been granted for:

- accepting, after obtaining, cryo-preserving and storing umbilical cord blood for autologous application in order to supply this material for applying it immediately on humans.

\* The original text has an incorrect number *Pf*



the recognition as an organ bank, with register number 108153 L/EO, is extended with the following actions and tissues:

- accepting, after obtaining umbilical cord blood, umbilical cord tissue and fat tissue, (obtained after liposuction) and importing this material to Dutch territory.
- accepting, after obtaining, cryo-preserving and storing umbilical cord tissue and fat tissue shall take place in order to supply this body material for further processing as medicine.

### **Decision**

Following the aforementioned I hereby send my decision, whereby you are granted the changed recognition as an organ bank, with register number 108153 L/EO, as from 28 April 2010. Article 9, first paragraph, of the Law for Safety and Quality of Human Material (Wvkl)

Our reference  
Farmatec-BMC/JZ-9659

### **Changes**

If you would like to introduce a change with regard to something that has been decided in your recognition, you must submit an application for change of your recognition to me. You can pass on these changes through a letter; no change application forms are available.

### **Objection clause**

You or other interested parties can object against this decision by virtue of article 7:1 of the General Administrative Law Act. This can be done by submitting a notice of objection to:

Ministry of Health, Welfare and Sport  
Management Legislation and Legal Affairs  
PO BOX 20350  
2500 EJ The Hague

The period for submitting a notice of objection is six weeks. This period shall start on the day after which the decision has been dated.

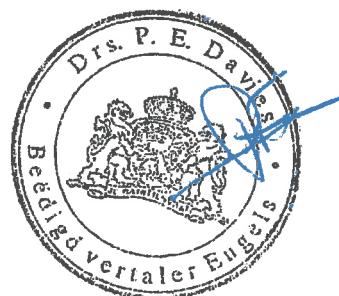
The notice of objection must be signed by the submitting party and include at least the following details:

- the name and address of the submitting party;
- the date
- a description of the contested decision, for example by stating the letter reference and the date, or a copy of the decision;
- the grounds of the objection.

Number 9659 applied to this application. I would like to ask you to always state this number with any correspondence and have it at hand during phone calls.

I will send a copy of this letter to the work fields in question of IGZ.

The Minister of Health, Welfare and Sport,  
On behalf of the Minister  
The unit Farmatec-BMC  
[signature]  
Mrs. Mr. A. J. Hennis  
Deputy unit manager





2011 / ED / 1047

**FAGG**

Federal Agency for Medicines and Health Products

Health Products Department  
"Blood and Human Cells and Tissues"

Federal Agency for Medicines and Health Products

OUR REF. KV/PB/VB/JV/XD/11060 257436  
DATE: 8 APRIL 2011  
REGISTERED +ACKNOWLEDGEMENT OF RECEIPT

CONTACT: Kimberley Vanthuyne  
TEL: 02 524 83 76  
FAX: 02 524 80 01  
E-MAIL: [Kimberley.vanthuyne@fagg.be](mailto:Kimberley.vanthuyne@fagg.be)

Dr Sally Sennitt  
Administrator human cells and tissues  
Cryo-Save Labs  
Galileilaan 19  
2845 Niel

**Institute for human cells and tissues: Notification of accreditation**

**Dossier FAGG no. 10 0003**

Name of the institute: **Cryo-Save Labs**  
Registered office: Galileilaan 19 – 2845 Niel  
Kind of institute: **Intermediate structure for human cells and tissues**  
Full address of place of business: Galileilaan 19 – 2845 Niel

Type of human tissue and/or activity: **processing, preservation, storage and distribution of cord blood, stem cells from the umbilical cord and adipose stem cells.**

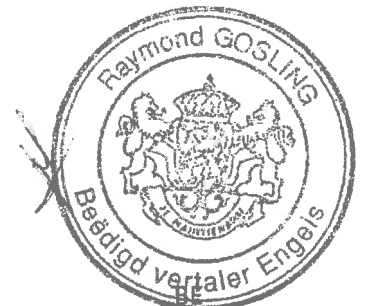
**Having regard to inspection no. DGI/RAP\_MLM/DMU\_EMD\_RDN/2010/051, carried out by the Federal Agency for Medicines and Health Products on 29 October 2010, accreditation is granted to the aforementioned institute from 1 December 2009 to 31 March 2012.**

This accreditation is granted by virtue of the Act of 19 December 2008 concerning the procurement and use of human cells and tissue with a view to medical application in humans or scientific research and its application decisions, transposing the European Directives 2004/23, 2006/17 and 2006/86.

**Rationale:**

The inspection report referred to above mentions several cases of non-compliance with the legislation and regulations, for example with article 17, paragraph 4 of the Act: there is no proof that the risks described in this article are covered by an insurance policy.

Federal Agency for Medicines and Health Products  
Eurostation II- Victor Hortaplein 40/40 – 1060 Brussels  
0884.579.424  
[www.fagg.be](http://www.fagg.be)





# Certificate of Registration

**QUALITY MANAGEMENT SYSTEM - ISO 9001:2008**

*This is to certify that:*

**Cryo-Save Labs  
Galileilaan 19  
B 2845 Niel  
Belgium**

*Holds Certificate No:* **FM 578312**

*and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:*

Receipt, processing, cryo-preservation, storage and release of umbilical cord blood, cord tissue and fat tissue for the purpose of autologous and directed allogeneic cell transplantation in humans.

*For and on behalf of BSI:*

*Chair, Certification Body Management Committee.*

Originally registered: **11/11/2011**

Latest Issue: **11/11/2011**

Expiry Date: **11/11/2014**



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated [online](#). Printed can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +44 (0)20 8996 7033.

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BSI (EMEA) Headquarters: 389 Chiswick High Road, London, W4 4AL, United Kingdom

