

18 March 2016

Betty Klein  
GyneConcepts, Inc.  
375 Thornwood Drive, N.E.  
Atlanta, GA 30328  
USA

Dear Betty:

I am writing to inform you we have notified the Competent Authority in the following countries:

- **The Netherlands**
- **Belgium**
- **Bulgaria**
- **Cyprus**
- **Croatia**
- **Greece**
- **Iceland**
- **Italy**
- **Liechtenstein**
- **Slovenia**
- **Slovakia**

With this notification, GyneConcepts, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- **PPS™ Personal Pap Smear™ Kit**

As of today and without any further notice from the respective Competent Authorities, GyneConcepts, Inc. can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,



Rene van de Zande  
Director  
Emergo Europe