

18 March 2016

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

Dear Betty:

I am writing to inform you that today, we have notified the Dutch Competent Authority.

With this notification, GyneConcepts, Inc. has met the requirements of Article 14 of the Medical Devices Directive, 93/42/EEC for the following devices:

- **PPS™**

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