



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Gynemed GmbH & Co. KG
Lübecker Str. 9 – 23738 Lensahn
Germany

has introduced and applies a Quality Management System
for the products / product category

Density Gradient system for cell separation
including semen separation

An Audit demonstrated compliance of the Quality Management System with

Annex V

of the **Council Directive 93/42/EEC concerning Medical Devices.**

The certification assumes that the company is applying and maintaining its Quality Management System according to the above given annex. The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 27 July 2014
Hamburg, 31 August 2010

Process No.: QS - 6587
Certificate No.: 6587GB414100831
MEDCERT Identification No.: 0482


MEDCERT Certification Body
(Dr. Andreas Schich)



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-983.94.13