



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

SOMATEX Medical Technologies GmbH
Rheinstrasse 7d – 14513 Teltow
Germany

has introduced and applies a Quality Management System
for the aspects of manufacture concerned with
securing and maintaining sterile conditions
for the products / product categories

- **Products for In-Vitro Fertilization and Assisted Reproduction Medicine:**
 - **Cervix catheters, Transfer catheters**
 - **Insemination catheters**
 - **Embryo transfer sets**
 - **ART syringes**
 - **ART mandrins**
 - **Aspiration tubes**
- **Adapters, Connectors, Hubs**
- **Fixation devices for marking wire systems**
- **Mixing devices and Injection systems for Vertebroplasty**

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: 23 July 2019

Hamburg, 12 November 2014

Process No.: QS - 7253

Certificate No.: 7253GB415141112

MEDCERT Identification No.: 0482

MEDCERT Certification Body
(Rainer Klatt)



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