



## 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 products / product categories

- **Biopsy systems, Biopsy cannulas**
- **Puncture cannulae and Puncture systems, Injection cannulas**
- **Marking wire systems, Localization kits**
- **Drainage catheters**
- **Intrauterine shunts**
- **Brachytherapy catheters**
- **Hyperthermie catheters**
- **Products for In-Vitro Fertilization and Assisted Reproduction Medicine:**
  - **Follicle Aspiration Sets**
  - **Follicle Aspiration Needles**
- **Cannulas and Application systems for Vertebroplasty**

An Audit demonstrated compliance of the Quality Management System with

### **Annex II**

excluding section (4)

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.: 7253GB410141112

MEDCERT Identification No.: 0482

MEDCERT Certification Body  
(Rainer Klatt)



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
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