



## Certificate

### The Certification 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 in the area of

**Design and Development, production and distribution of  
medical devices**

**See attachment**

A Quality Audit demonstrated compliance of the Quality Management System with

**EN ISO 13485:2012 + AC:2012**

The certification assumes that the company is applying and maintaining its  
Quality Management System according to the above given standard.


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.: 7253GB438141112

  
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MEDCERT Certification Body  
(Rainer Klatt)



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-983.99.02-46




## Attachment Certificate QS - 7253

- **Biopsy systems, Biopsy cannulas**
- **Puncture cannulas and Puncture systems, Injection cannulas**
- **Marking wire systems, Localization kits**
- **Fixation devices for marking wire systems**
- **Drainage catheters**
- **Intrauterine shunts**
- **Brachytherapy catheters**
- **Hyperthermie catheters**
- **Adapters, Connectors, Hubs**
- **Products for In-Vitro Fertilization and Assisted Reproduction Medicine:**
  - **Follicle Aspiration Sets**
  - **Follicle Aspiration Needles**
  - **Cervix catheters, Transfer catheters**
- **Insemination catheters**
  - **Embryo transfer sets**
  - **ART syringes**
  - **ART mandrins**
  - **Aspiration tubes**
- **Products for Vertebroplasty:**
  - **Cannulas and Application systems**
  - **Mixing devices and Injection systems**

The attachment is valid only in connection with  
certificate-No: 7253GB438141112

Hamburg, 12 November 2014

  
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(Rainer Klatt)



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