

# EC Certificate of Conformity

## The Notified Body

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

herewith certifies that the company:

**SOMATEX Medical Technologies GmbH**  
**Hohenzollerndamm 150/151**  
**14199 Berlin**  
**Germany**

with locations listed in the appendix

has introduced and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design-examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

## This certificate is valid until 27 May 2024

Report No.: 7253FS08F  
Process No.: QS – 7253  
Certificate No.: 7253GB410190814

Hamburg, 14 August 2019

  
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MEDCERT Certification Body  
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).

MEDCERT Identification Number: 0482



## Appendix of EC Certificate of Conformity

Process No.: QS – 7253

Certificate No.: 7253GB410190814

### List of locations included in the scope of certificate

**SOMATEX Medical Technologies GmbH  
Blankenfelder Dorfstrasse 94  
15827 Blankenfelde-Mahlow  
Germany**

– End of list –

This appendix is integral part of the above-referenced certificate.  
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**Appendix of EC Certificate of Conformity**

Process No.: QS – 7253

Certificate No.: 7253GB410190814

**List of products / product categories included in the scope of certificate**

- **Biopsy systems**
- **Biopsy cannulas**
- **Marking wire systems, Localization kits**
- **Hyperthermia catheters**
- **Products for In-Vitro Fertilization and Assisted Reproduction Medicine**
  - **Follicle Aspiration Sets**
- **Cannulas and Application systems for Vertebroplasty**

– End of list –

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