

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
Hohenzollerndamm 150/151
14199 Berlin
Germany**

With its facility as per attachment 1

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, final inspection and distribution of
Medical devices as per attachment 2**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:


EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 23 July 2022

Report No.: 7253FS08F
Process No.: QS-7253
Certificate No.: 7253GB445190814

Hamburg, 14 August 2019



MEDCERT Certification Body
(Dr. Andreas Schich)

**DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

**Attachment 1
Certificate
QS - 7253**

This attachment is valid only in connection with certificate No.: 7253GB445190814

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

Hamburg, 14 August 2019



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Attachment 2
Certificate
QS - 7253

This attachment is valid only in connection with certificate No.: 7253GB445190814

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

Hamburg, 14 August 2019



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