

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 aspects of manufacture concerned with securing and maintaining sterile conditions

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 V

This certification is subject to surveillance by MEDCERT.

This certificate is valid until 27 May 2024

Report No.: 7253FS08F
Process No.: QS – 7253
Certificate No.: 7253GB415190814

Hamburg, 14 August 2019


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.

MEDCERT Identification Number: 0482

Form F10010014e EN / Rev. 8 / 2019.05.22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 7253

Certificate No.: 7253GB415190814

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.: 7253GB415190814

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

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

– End of list –

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