

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, applies 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.

Effective date: 2021-03-03
Expiry date: 2024-05-27

Report No.: 7253PS09F
Process No.: QS – 7253
Certificate No.: 7253GB410210303A

Hamburg, 2021-03-03


MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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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.: 7253GB410210303A

List of locations included in the scope of certificate

**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.: 7253GB410210303A

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

- **Biopsy systems**
- **Biopsy cannulas**
- **Marking wire systems, Localization kits**

[REDACTED]

[REDACTED]

- **Intrauterine Shunts**

– End of list –

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