

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1985746-1

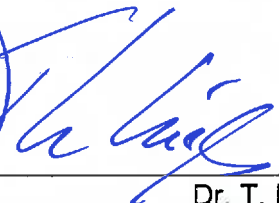
Organization: Somatex Medical Technologies GmbH
Hohenzollerndamm 150-151
14199 Berlin
Germany

Scope: Design and development, manufacture and distribution of biopsy systems, biopsy cannulas, wire marking systems, localization sets and intrauterine shunts.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3342768-90
Effective date: 2022-08-25
Expiry date: 2025-08-04
Issue date: 2022-08-25




Dr. T. Kießling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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Germany

The scope of certification covers the following:

No.	Facility	Scope
/01	c/o Somatex Medical Technologies GmbH Hohenzollerndamm 150-151 14199 Berlin Germany	Design and development, manufacture and distribution
/02	c/o SOMATEX Medical Technologies GmbH Warehouse Blankenfelder Dorfstr. 94 15827 Blankenfelde-Mahlow Germany	Manufacture and distribution

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