



# Certificate

No. Q6 003430 0007 Rev. 00

**Holder of Certificate:** **Biometrix s.r.o**

Vicenzy 16  
93101 Samorin  
SLOVAKIA

**Facility(ies):**

Biometrix s.r.o  
Vicenzy 16, 93101 Samorin, SLOVAKIA

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:**

**Manufacturing and Distribution of Catheters and Drainage systems, Tubing for vascular use, Vascular Catheters, Guide Wires, Suction tubes and probes, fluid management system for infusion, irrigation, non-invasive physiological & blood pressure monitoring systems, angiographic kits, for preparation of PTCA, Procedure packs of various combinations.**

**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6\\_003430\\_0007\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:Q6_003430_0007_Rev.00)

**Report No.:** IND2021019

**Valid from:** 2022-10-07

**Valid until:** 2025-05-07

**Date,** 2022-10-07



Christoph Dicks  
Head of Certification/Notified Body