



Certificate

No. Q5 003430 0004 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

Certification Mark:



Scope of Certificate:

Design and Development, 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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

IND2018031

Valid from:

2019-06-06

Valid until:

2022-05-07



Date, 2019-06-06

Stefan Preis
 Head of Certification/Notified Body