



# Certificate

No. Q5 002374 0009 Rev. 00

**Holder of Certificate:** **BIOMETRIX LIMITED**  
4 Kiryat Mada  
9145000 Jerusalem  
ISRAEL

**Certification Mark:**



**Scope of Certificate:** Design and development, production and distribution of Intra vascular Catheters and foley catheters.  
Production and distribution of Fluid output and pressure measurement devices, complete drainage systems, reservoirs, catheters and drains, elastic tubing for vascular use, guide wires, extracorporeal tubing sets and accessories, suction tubing and probes, needles, complete fluid management system for infusion, irrigation and feeding, invasive physiological & non active components for blood pressure monitoring systems, catheter-sets for radiology and angioplasty procedures, obstetrics and newborn accessories & custom procedure packs including various combinations of the above listed devices.

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). 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:Q5 002374 0009 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_002374_0009_Rev._00)

**Report No.:** IND2020121

**Valid from:** 2021-10-28  
**Valid until:** 2024-01-31

**Date,** 2021-10-28



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):**

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

**Facility(ies):**

BIOMETRIX LIMITED  
4 Kiryat Mada, 9145000 Jerusalem, ISRAEL

See Scope for Certificate

BIOMETRIX LIMITED  
Pirhey Hahar 3, Har Tuv Industrial area B, 9900000 Bet Shemesh,  
ISRAEL

See Scope for Certificate

Shomrat Molds LTD  
Industrial Zone, 1030000 Hatzor Haglilit, ISRAEL

See Scope for Certificate

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