



Certificate

No. Q5 106138 0001 Rev. 01

Holder of Certificate: **Marflow AG**
Alte Landstrasse 54
8546 Islikon
SWITZERLAND

Certification Mark:



Scope of Certificate: Design & Development, Manufacturing and Distribution of Sterile & Non- Sterile products including Total & Partial Hip Replacement System, Total & Partial Knee Replacement System, Spine Fixation Implant, TURP Loop, Scope & Control Unit, Thulium Fiber Laser Equipment, Fiber Laser and Accessories, Suction and Irrigation Equipment, RIRS Kit, Dilators & Set, Double J Stents/Ureteral Stents & Kit, Stone Basket, Graspers, Forceps, Guidewires, Needles, Amplatz Dilators & Kit, Ureteral Catheters, Nephrostomy Catheters (PCN), Malecot Catheter, Fascial Dilators, Ureteral Dilators, Ureteral & Nephrostomy Balloon Dilators, Stents, Stents & Deployer, Suprapubic Catheter, Cystocatheter & Kit, Morcellator & Accessories, Ureteral Access Sheath, Evacuator, Penile Clamp, Biopsy gun, Biopsy Needle, Forceps, Urine Bag, Incontinence Sling, Hypospadias Kit, Biliary Stents -Metal & Plastic & Deployer, Esophageal Metal Stent & Deployer, Gastro Balloon Dilators, Forceps, Loop Baskets, Biopsy Forceps, Polypectomy Snare, PEG Kit, Gastro Guidewires, Biliary Dilators, Pancreatic Stents, Biliary Stent Introducer, Gastro Baskets, Cleaning Brushes, Hemoclip, NBDCatheter, PTDB Catheter & Kit, Sphincterotome, NasoJejunal Feeding Tube, Bilbao Dotter Tube, Multiband Ligator & Kit, Sclerotherapy Needle, Hemoroid Gun, FNA & FNB Needle, Mechanical lithotripter, Cytology Brush, Cleaning Brush, Bite Guard, Extracorporeal Shock wave Lithotripsy (ESWL), Balloon and other Medical Disposables, Surgical Tools , Equipment & Accessories in the field of Cardiovascular, Electrosurgical Applications, Gastroenterology, Neurology, Gynaecology, Orthopaedic, Radiology & Urology.

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_106138_0001_Rev.01

Report No.: 201530000348_CN
Valid from: 2024-10-29
Valid until: 2026-06-19



Date, 2024-10-29

Christoph Dicks
Head of Certification/Notified Body



Product Service

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Marflow AG**
Alte Landstrasse 54, 8546 Islikon, SWITZERLAND

See Scope of Certificate

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