



CERTIFICATE

No. QS2 048250 0005 Rev. 08

Certificate Holder:

**Precision Concepts Costa Rica, S.A.
Doing Business as Biomerics Alajuela**
Building D-3, C-1, C-7, C-2/C-3, C-4,E-2
Saret Industrial Park
4002 Alajuela
COSTA RICA

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard:

ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

721019593

Effective Date:

2026-09-19

Expiry Date:

2029-09-18

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Date of Issue: 2026-09-04

(Sofia Epshtein Elbrus)
Director, US Certification Body, MHS



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Overall Scope Statement:

Contract Manufacturer of Fetal Monitoring Devices and Accessories, Water Trap Assemblies for Gas Detection Systems, Intravenous Disposable Devices, Cable Assemblies for Electrocardiography and SpO2 Monitoring Devices, Cable for Specialized Medical Devices and Cable Subassembly for Medical and Surgical Applications, Needle Subassemblies, Nerve Ablation Probe, Autoinjector Assembly for Endovascular Aortic Repair, Vertebral Compression Fractures Subassemblies, Angiography Products and Accessories, Electrosurgical, Cutting and Coagulation and Accessories, Blood Collection Device and Accessories; Manufacture and Packaging of Balloon Sinuplasty Devices, Accessories for Otolaryngology, Endoscopy Instruments and Accessories, Catheter Subassemblies for Cardiovascular Applications; Molding of Plastic Components; and Sterilization Management; Manufacture of Sterile Diagnostic Catheters, Infusion Catheters, Implantable Infusion Ports and Accessories; Manufacture and Packaging of Spinal Implants and Related Prep and Delivery Instruments; Manufacturing, Assembly and Testing of Medical Devices and Accessories for Targeted Cryotherapy

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