

# Certificate



**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2219429-1

Organization: Proven Process Medical  
Devices, Inc.  
110 Forbes Boulevard  
Mansfield MA 02048  
USA

Scope: Subcontracted Design and Development for Medical Devices, Active  
Implantable Medical Devices and In Vitro Diagnostic Medical Devices


Subcontracted Manufacturing and Servicing of Medical Devices, Active  
Implantable Medical Devices and In Vitro Diagnostic Medical Devices  
including Mechanical and Electromechanical Systems, Assemblies and  
Metal Parts

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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