

# Certificate



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

Registration No.: SX 2094002-1

Organization: Shenzhen Envisen Industry Co., Ltd.  
Block 1, Room 201,301,401, 40 Jianlong Street,  
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Scope: Design and Development, Manufacture and Distribution of Oximeter  
Probes, Temperature Probes, Breathing Circuits, Head Positioning  
Devices, NIBP Cuffs, Medical Cable Assemblies, Pulse Oximeters, Pulse  
Oximeter Modules, Anaesthetic Gas Sampling Line

  
TÜVRheinland®

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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