

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 2094002-1

Certificate Holder: Shenzhen Envisen Industry Co., Ltd.  
Block 1,  
Room 201,301,401, 40 Jianlong Street,  
Baoan Community, Yuanshan Town,  
Longgang District,  
Shenzhen,  
518115 Guangdong  
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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 Lines, Sterile Foley Catheters with  
Temperature Probes

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.

Report No.: 10920777-120  
Effective date: 2024-03-26  
Expiry date: 2026-03-15  
Issue date: 2024-03-26  
Replaces certificate SX 2094002-1 issued 2023-03-15

This certificate can be validated on <https://www.certipedia.com>

  
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