

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 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
P.R. China

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, Eye Protectors

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.: 10926940-110
Effective date: 2026-03-16
Expiry date: 2029-03-15
Issue date: 2026-03-10
Replaces certificate SX 2094002-1 issued 2024-03-26

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


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