



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Envisen Industry Co., Ltd.
2nd Floor, Block 1
40 Jianlong Street, Baoan Community
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Oximeter Probes, Temperature Probes, Breathing Circuits,
Head Positioning Devices, NIBP Cuffs, Medical Cable
Assemblies, Pulse Oximeter, Pulse Oximeter Modules**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-08-04

Certificate Registration No.: SX 60119467 0001

An audit was performed. Report No.: 17023744 009

This Certificate is valid until: 2019-02-28

Certification Body



Date 2017-08-04



S. Liu

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