

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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 Oximeters, Pulse Oximeter Modules

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2020-06-23
Certificate Registration No.: SX 60147401 0001
An audit was performed. Report No.: 17023744 015
This Certificate is valid until: 2023-03-15

Certification Body



Date 2020-06-23



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