

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

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>