

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60116712 0001

**Report No.:** 17023744 008

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

**Products:** Oximeter Probes, Temperature Probes, Breathing Circuits,  
Pulse Oximeters

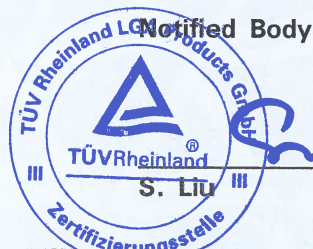
Replaces Approval, Registration No.: HD 60104774 0001

**Expiry Date:** 2022-03-15

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-03-16

**Date:** 2017-03-09



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.