

## EC Declaration of Conformity

**Manufacturer:**

*whose single Authorized Representative:*

**Shenzhen Envisen Industry Co., Limited**  
2nd Floor, Block 1, 40 Jianlong Street,  
Baoan Community, Heng Gang Town,  
Long Gang District, Shenzhen,  
China 518115

**Sensatronic GmbH**  
Alter Holzhafen 19  
23966 Wismar  
Germany

We, the manufacturer, herewith declare that the products

## Probes, Pulse Oximeter, Single use

GMDN-Code/Preferred Terms:31658

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**  
 Certificate No.: HD 60116712 0001

Issue date: 2017-03-16  
Expiry date: 2022-03-15

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

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Heng Gang Town, Long Gang District, Shenzhen,  
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Shenzhen, 2017.7.13

Place, date

*Legally binding signature*