ENVISEN
深圳安维森实业有限公司

2017-07-13

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, Resuable
GMDN-Code/Preferred Terms:37808

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

CE 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

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

Shenzhen, 2017.7.13 _____ _____

Place, date *Legally binding signature*