

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

Shanghai International Holding Corp. GmbH
(Europe)
Eiffestrasse 80, 20537 Hamburg , 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 60147402 0001

Issue date: 2020-06-23

Expiry date: 2024-05-26

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

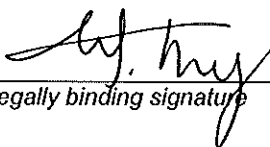
Block 1, Room 201, 301, 401, 40 Jianlong Street, Baoan Community, Yuanshan Town,
Longgang District, Shenzhen, China
518115

Ailsa Huang / Management Representative

Shenzhen, 2020.7.7

Name/ Function

Place, date


Legally binding signature