EC Declaration of Conformity

Manufacturer:

Shanghai Huazhe International Co.,ltd
Room F, 6/Floor, Building 6, No. 1369
Dongfang Road, Shanghai, 200127, P. R China

whose single Authorized Representative:

Lotus Global Co.，Ltd
15 Alexandra Road London UK
NW8 0DP

We, the manufacturer, herewith declare that the products

Product name: **Pulse Oximeter**

Type(s): HZ-A2, HZ-A3, HZ-A4, HZ-C21, HZ-300, HZ-CF315

UMDNS-Code: **[17-148]**
meet the provisions of Directive 93/42/EEC which apply to them.

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

CE 0197

The product concerned has been manufactured under a quality management system according to Annex Vof 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.: 60108879 0001
Issue date: 2018-05-25
Expiry date: 2023-05-24

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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: Shanghai Huazhe International Co., Ltd.
Address: Room F, 6/Floor, Building 6, No. 1369 Dongfang Road, Shanghai, 200127, P. R China

Shanghai huazhe China,2018-05-30
Place, date

上海华浙国际贸易有限公司
SHANGHAI HUAZHE INTERNATIONAL CO LTD

Mr.JackyZhu.manager
Legally binding signature, Function