

EC Declaration of Conformity

Manufacturer:

Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Address1: Building 2, No.202, Zhenzhong Road, West
Lake Economy &. Technology Zone, Hangzhou, China
Address2: No.3, 1st Street, YuHang Economic
Development Zone, Hangzhou, China

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Digital Thermometer

Model: ET-101H (CTM model: Medel Ear Temp)

UMDNS-Code: 14036

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

The medical device has been assigned to class IIa by rule 10 according to Annex IX of the Directive 93/42/EEC.

It bears the mark

C E 0197

The product concerned has been evaluated under technical files compliance according to Annex VII, and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 60137410 0001

Issue date: 2019-06-03

Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex V 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: Sejoy Electronics & Instruments Co., Ltd.

Address1: Building 2, No.202, Zhenzhong Road, West Lake Economy &. Technology Zone, Hangzhou, China

Address2: No.3, 1st Street, YuHang Economic Development Zone, Hangzhou, China

Hangzhou, June 05, 2019

Place, date

Q04-MT0JS-001(-03B) Version: B/3



General Manager

杭州世佳电子有限公司
Legally binding signature, Function
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.