

EC Declaration of Conformity

Manufacturer:

JOYTECH HEALTHCARE CO. LTD.
Address: No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100 Zhejiang, China

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Probe cover of Infrared Ear Thermometer

Model: DET-101, DET-102, DET-103, DET-105

Note: Probe covers are used as accessories of the Infrared Ear thermometers and registered with the Infrared Ear thermometers as a whole machine according to Annex V of Directive 93/42/EEC. They can be sold separately or together with the thermometers

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

CE 0197

The product concerned has been 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.: DD60147728 0001

Issue date: 2020-04-07

Expiry date: 2024-05-26

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: JOYTECH HEALTHCARE CO., LTD.

Address: No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100
Zhejiang, China

Hangzhou, Apr 14th, 2020

Place, date

JO-DET02-04

Version:A/2



General Manager

Legally binding signature. Function

