JOYTECH 健拓 JOYTECH HEALTHCARE CO. LTD.

EC Declaration of Conformity

Manufacturer:

JOYTECH HEALTHCARE CO. LTD.

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

whose single Authorized Representative:

Medical Device Safety Service GmbH

Schiffgraben 41,30175 Hannover, Germany

We, the manufacturer, herewith declare that the products

Veroval® DS 22 Infrared Ear/Forehead Thermometer

Model: DET-219,DS 22

Probe Cover of Infrared Thermometer

Model: PC 22

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 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.: DD601477280001

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

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

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Hangzhou, April 28th, 2020

Place , date

JOYTECH HEALTHCARE CO.,LTD
浙江健拓医疗仪器科技有限公司