

EC Declaration of Conformity

Manufacturer:

K-JUMP HEALTH CO., LTD
NO.56, Wu Kung 5th Rd., New Taipei Industrial Park,
New Taipei City 24890, Taiwan

whose single Authorized Representative:

POLYGREEN GERMANY GmbH
Ruhlsdorfer Straße 95, D-14532, Stahnsdorf,
Brandenburg, Germany
DIMDI Code: DE/0000044710

We, the manufacturer, herewith declare that the products

KD-1290(SC70), KD-1211(SC 44 flex), KD-122(SC 33 TM), KD-132(SC37T/
SC35T), KD-133(SC19 flex), KD-1351(SC17/SC18), KD-1471(SC28 flex),
KD-1501(SC41flex), KD-153(SC19 flex), KD-181(SC 42TM), KD-1491(SC29
flex), KD-2050 (SC 2050), KI-8172 (SC 8172), KI-8178 (SC 8178), KI-8271
(SC 8171), **KI-8280 (SC 8280)**

CLINICAL ELECTRONIC THERMOMETER

UMDNS-Code: 14-032

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



The product concerned has been designed and manufactured under a quality management system according to Annex II (without the Annex II.4) of Directive 93/42/EEC and the essential requirement of Annex I pertaining to medical devices.

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

Registration No.: HD 60107452 0001

Issue date: 01.02.2016

Expiry date: 31.01.2021

following the procedure relating to the EC Declaration of Conformity set out in Annex II and Annex VII 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

K-JUMP HEALTH CO., LTD

K-JUMP HEALTH CO.,LTD.

Taipei, 2020-04.29

Place, Date

Natalie Guo / Sales Director

