

SUZUKEN CO., LTD.

8 HIGASHI KATAHA-MACHI, HIGASHI-KU, NAGOYA, AICHI 461-0015 JAPAN

EC Declaration of Conformity

We SUZUKEN COMPANY LIMITED
8 Higashikataha-machi, Higashi-ku,
Nagoya, Aichi 461-8701 JAPAN

Declare under our sole responsibility that the product,

Type of Product: Electrocardiograph

Model Number: Kenz ECG 108, 110
Kenz Cardico 302, 601, 1210, 1211

Intended use: Class IIa medical device with the measuring function for
electrocardiography to which this declaration relates is in conformity
with the Medical Device Directive (93/42/EEC).

Notified Body: LNE/G-MED CE 0459
MEDICAL DEVICE ASSESSMENT BODY
Head office
1, rue Gaston Boissier - 75724 Paris Cedex 15 France

Certificate No. Annex II.3 No.11882 Rev.2

Issue date: November 28, 2010

Representative agent: Obelis s.a.

Location of the representative: Boulevard Général Wahis 53, 1030 Brussels, BELGIUM

Tel: +32 2 732 59 54 Fax: +32 2 732 60 03

Signed on this date: February 1, 2011

LNE/G-MED (0459) reconnaît que son certificat CE
est valide pour les dispositifs médicaux décrits

LNE/G-MED (0459) recognizes that its EC certificate
is valid for the medical devices listed

Luc CHAUSSON April 18th, 2011



Katsuya Iwasaki
General Manger
Kenz Product Department



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8 Higashikataha-machi, Higashi-ku,
Nagoya, Aichi 461-8701 JAPAN

Declare under our sole responsibility that the product,

Type of Product: Ambulatory Electrocardiograph

Model Number: Kenz Cardy 301, 301L, 302

Intended use: Class IIa medical device with the measuring function for
electrocardiography to which this declaration relates is in conformity
with the Medical Device Directive (93/42/EEC).

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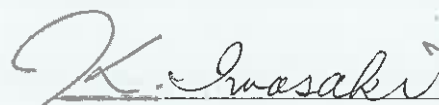
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Katsuya Iwasaki

General Manager

Kenz Product Department



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Declare under our sole responsibility that the product,

Type of Product: Ambulatory Electrocardiograph software

Model Number: Kenz Cardy Analyzer 03 Type-S, 05 Type-S

intended use: Class IIa medical device for Ambulatory Electrocardiograph software
to which this declaration relates is in
conformity with the Medical Device Directive (93/42/EEC).

Notified Body: LNE/G-MED CÉ 0459
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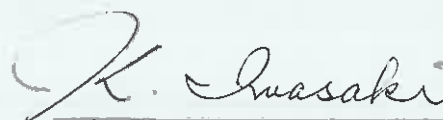
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Declare under our sole responsibility that the product,

Type of Product: Accessory of Ambulatory Electrocardiograph

Model Number: Kenz Cardy Controller

Intended use: Class IIa medical device with the measuring function for
electrocardiography to which this declaration relates is in conformity
with the Medical Device Directive (93/42/EEC).

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Declare under our sole responsibility that the product,

Type of Product: ECG data viewer software

Model Number: Kenz ECG Data Viewer

Intended use: Class IIa medical device with the measuring function for
ECG data viewer software to which this declaration relates is in
conformity with the Medical Device Directive (93/42/EEC).

Notified Body: LNE/G-MED CE 0459
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