

EC Certificate Full Quality Assurance System: Certificate
Certificate JP05/040100

The management system of

Parama-Tech Co., Ltd.

1-7-5 Tanotsu, Higashi-ku, Fukuoka-shi, Fukuoka-ken Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Personal Electrocardiogram Recorder
(Model:EP-201C, EP-202C, EP-301C)**

**Automatic Infusion Control Equipment NE-1 with designated name:
Drip-EYE**

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 18 August 2013 until 18 August 2018 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 August 2016
Issue 9. Certified since 8 June 2005

Certification is based on reports numbered JP/YOK/2473

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS

Certificate JP05/040098

The management system of

Parama-Tech Co., Ltd.

1-7-5 Tanotsu, Higashi-ku, Fukuoka-shi, Fukuoka-ken Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Design, manufacture and repair of Personal ECG Recorder,
automatic infusion control equipment and electronic sphygmomanometer**

This certificate is valid from 18 August 2013 until 18 August 2016 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 August 2016
Issue 6. Certified since 24 January 2005

Authorised by



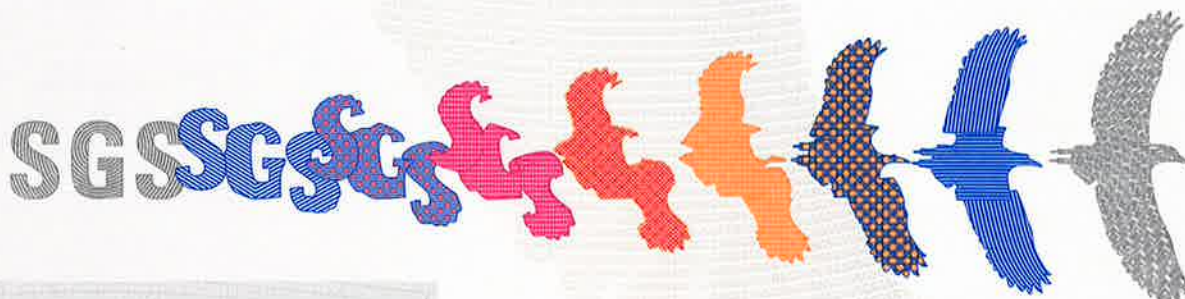
SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0612

Page 1 of 1



005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

The management system of

Parama-Tech Co., Ltd.

1-7-5 Tanotsu, Higashi-ku, Fukuoka-shi, Fukuoka-ken Japan

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Design, manufacture and repair of physiological function measuring equipment and automatic infusion control equipment

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

This certificate is valid from 18 August 2013 until 18 August 2016 and remains valid subject to satisfactory surveillance audits
Re certification audit due before 18 August 2016
Issue 5 Certified since 24 January 2005

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3 EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0311

Page 1 of 1



005

