Certificate JP08/040040

2008 年 2 月 6 日 (Copy)

The management system of

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

NIIGATA FACTORY 96 Yoshida-Kounosu, Tsubame-shi,
Niigata-ken Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

The scope of registration appears on page 2 of this certificate

This certificate is valid from 21 January 2008 until 21 July 2011
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 21 January 2008
Recertification Audit due 21 January 2011

This is a multi-site certification.
Additional site details are listed on subsequent pages.

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

Digitally signed by Grabazei Alexandru
Date: 2019.03.21 09:59:08 EET
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Location: Moldova

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2008年 2月 6日 (Copy)

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

ISO 13485:2003

Issue 1

Detailed scope

1. Design, development, manufacture and sales of sterile and non-sterile medical suture materials, surgical instruments, sterile and non-sterile titanium plate system, sterile and non-sterile surgical blades, sterile angiographic catheters, sterile intravascular catheters, sterile snare catheters, sterile micro catheters, sterile hæmostatic catheters.
2. Design, development, manufacture, sales and servicing of electrosurgical system and air fluidized support system.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organization

Additional facilities

TOKYO SERVICE CENTER	3-19-6 Hongo, Bunkyo-ku, Tokyo Japan
OSAKA SERVICE CENTER	1-8-14 Nakatsu, Kita-ku, Osaka-shi, Osaka Japan
KYUSHU SERVICE CENTER	2-9-1 Hakataeki-Higashi, Hakata-ku, Fukuoka-shi, Fukuoka-ken Japan
SAPPORO SERVICE CENTER	4-2-3 Kita 38 jyo Nishi, Kita-ku, Sapporo-shi, Hokkaido Japan

Certificate JP08/040042

2008年 2月 6日 (Copy)

The management system of

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

96 Yoshida-Kounosu, Tsubame-shi, Niigata-ken Japan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4)

For the following products

PGA Synthetic Absorbable Sutures, Sterile surgical stapler

This certificate is valid from 21 January 2008 until 21 July 2011
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 21 January 2008

Notified Body Number 0120

Authorised by

CE
0120

SGS United Kingdom Ltd Systems & Services Certification
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 1007

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(Copy)

Certificate JP08/040043

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

96 Yoshida-Kounosu, Tsubame-shi, Niigata-ken Japan

Device Identification:
PGA Synthetic Absorbable Suture

Medical Purpose of Device:
For use in soft tissue closure and/or ligation in surgical procedures.
Not for use in cardiovascular or neurological procedures.

has been assessed and certified as meeting the requirements of

EC Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to regular compliance visits.

This certificate is valid from 22 January 2008 until 22 January 2013
Issue 1

Certification is based on report number(s) JP/YOK/5585 dated 21 January 2008

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
N/A	N/A

Notified Body Number 0120

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
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Certificate JP08/040041

2008年2月6日 (Copy)

The management system of

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

NIIGATA FACTORY 96 Yoshida-Kounosu, Tsubame-shi, Niigata-ken Japan

has been assessed and certified as meeting the requirements of

ISO 9001:2000

For the following activities

The scope of registration appears on page 2 of this certificate

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organization

This certificate is valid from 21 January 2008 until 21 January 2011
Issue 1 Certified since 21 January 2008

This is a multi-site certification
Additional site details are listed on the subsequent page

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2008年2月6日 (Copy)

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

ISO 9001:2000

Issue 1

Detailed scope

1. Design, development, manufacture and sales of sterile and non-sterile medical suture materials, surgical instruments, sterile and non-sterile titanium plate system, sterile and non-sterile surgical blades, sterile angiographic catheters, sterile intravascular catheters, sterile snare catheters, sterile micro catheters, sterile hæmostatic catheters.
2. Design, development, manufacture, sales and servicing of electrosurgical system and air fluidized support system.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organization

Additional facilities

TOKYO SERVICE CENTER	3-19-6 Hongo, Bunkyo-ku, Tokyo Japan
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KYUSHU SERVICE CENTER	2-9-1 Hakataeki-Higashi, Hakata-ku, Fukuoka-shi, Fukuoka-ken Japan
SAPPORO SERVICE CENTER	4-2-3 Kita 38 jyo Nishi, Kita-ku, Sapporo-shi, Hokkaido Japan

UKAS QUALITY MANAGEMENT 005