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Certificate JP08/040040

SGS

The management system of

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

NIIGATA FACTORY 96 Yoshida-Konosu, Tsubame-shi, Niigata, 959-0261 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design, development, manufacture and sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use snare catheters, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system

Design, development, manufacture, sales and servicing of surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators

This certificate is valid from 30 January 2023 until 21 January 2026 and remains valid subject to satisfactory surveillance audits.

Issue 12. Certified since 21 January 2008

Certified activities performed by additional sites are listed on subsequent pages.

Jonathan M. Hall

Authorised by
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Certificate JP08/040040, continued

KEISEI MEDICAL INDUSTRIAL Co., Ltd.

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ISO 13485:2016
EN ISO 13485:2016

Issue 12
Sites
KEISEI MEDICAL INDUSTRIAL Co., Ltd. NIIGATA FACTORY 96 Yoshida-Konosu, Tsubame-shi, Niigata, 959-0261 Japan
Design, development, manufacture and sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use snare catheters, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system
Design, development, manufacture, sales and servicing of surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators
KEISEI MEDICAL INDUSTRIAL Co., Ltd. TOHOKU FACTORY 41-15-7 Taneichi, Hirono-cho, Kunohe-gun, Iwate, 028-7911 Japan
Manufacture of sterile single-use surgical skin stapler
KEISEI MEDICAL INDUSTRIAL Co., Ltd. TOKYO SERVICE CENTER 19-6 Hongo 3, Bunkyo-ku, Tokyo, 113-0033 Japan
Sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system, surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators



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KEISEI MEDICAL INDUSTRIAL Co., Ltd.

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ISO 13485:2016
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KEISEI MEDICAL INDUSTRIAL Co., Ltd. OSAKA SERVICE CENTER
1-9-10 Higashi-Tenma, Kita-ku, Osaka-shi, Osaka, 530-0044 Japan

Sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system, surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators

KEISEI MEDICAL INDUSTRIAL Co., Ltd. KYUSHU SERVICE CENTER
3-11-14 Hakataeki-Higashi, Hakata-ku, Fukuoka-shi, Fukuoka, 812-0013 Japan

Sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system, surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators

KEISEI MEDICAL INDUSTRIAL Co., Ltd. SENDAI SERVICE CENTER
2-1-7 Honcho, Aoba-ku, Sendai-shi, Miyagi, 980-0014 Japan

Sales of sterile absorbable and non-absorbable suture, sterile and non-sterile needles, sterile single-use blade for dermatome, sterile single-use surgical skin stapler, sterile single-use surgical clamps, non-sterile single use titanium fixation plate system, surgical instruments, electrosurgical system, electric dermatome, air fluidized support system and electromedical stimulators



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