

Certificate KR07/70934.00

The management system of

Tae-Chang Industrial Co., Ltd

(Gongju Plant) 8-18 Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016

ISO EN 13485:2016

For the following activities

Design, Development and Manufacture of sterile single use surgical needles including spinal needles, epidural needles, hypodermic needles, seldinger needles, lancet needles, umbilical cord clamp, bulk needles, cannula, sterile single use insulin syringe, sterile single use insulin pen needle, sterile single use needles for injecting filler and sterile single use endodontic irrigation needles;

Design and Manufacture of sterile single use blood bags.

This certificate is valid from 20 January 2022 until 20 January 2025 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 20 March 2013.

Certified activities performed by additional sites listed on subsequent pages.

Authorised by



SGS United Kingdom Ltd.

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

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Tae-Chang Industrial Co., Ltd

ISO 13485:2016

ISO EN 13485:2016

Issue 7
Sites
Tae-Chang Industrial Co., Ltd (Gongju Plant) 8-18 Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, Republic of Korea
Tae-Chang Industrial Co., Ltd 127, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Republic of Korea



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Certificate KR07/70934.01

The management system of

Tae-Chang Industrial Co., Ltd

(Gongju Plant) 8-18 Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016

ISO EN 13485:2016

For the following activities

Design, Development and Manufacture of sterile single use surgical needles including spinal needles, epidural needles, hypodermic needles, seldinger needles, lancet needles, umbilical cord clamp, bulk needles, cannula, sterile single use needles for injecting filler and sterile single use endodontic irrigation needles.

This certificate is valid from 20 January 2022 until 20 January 2025 and remains valid subject to satisfactory surveillance audits.

Issue 2.

Multiple certificates have been issued for this scope, the main certificate is numbered KR07/70934.00

The validity of this certificate depends on the validity of the main certificate

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Certificate KR07/70934.02

The management system of

Tae-Chang Industrial Co., Ltd

127, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Korea, Korea, Republic Of
has been assessed and certified as meeting the requirements of

ISO 13485:2016
ISO EN 13485:2016

For the following activities
Design, Development and Manufacture of sterile single use insulin syringe
and sterile single use insulin pen needle;

Design and Manufacture of sterile single use blood bags.

This certificate is valid from 20 January 2022 until 20 January 2025 and remains valid subject to satisfactory
surveillance audits.
Issue 2.

Multiple certificates have been issued for this scope, the main certificate is numbered KR07/70934.00
The validity of this certificate depends on the validity of the main certificate

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