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, 32533, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, Development and Manufacture of sterile single use surgical needles including spinal needles, epidural needles, hypodermic 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. Design and Manufacture of sterile single use blood bags.

This certificate is valid from 15 January 2025 until 20 January 2028 and remains valid subject to satisfactory surveillance audits.

Issue 9. Certified since 20 March 2013

Multiple certificates have been issued for this scope, the main certificate is numbered KR07/70934.00 Certified activities performed by additional sites are listed on subsequent pages.

C. Moran

Authorised by

Liz Moran

Business Manager

SGS United Kingdom Ltd

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

t +44 (0)151 350-6666 - www.sgs.com







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Certificate KR07/70934.00, continued

Tae-Chang Industrial Co., Ltd



ISO 13485:2016

EN ISO 13485:2016

Sites

Tae-Chang Industrial Co., Ltd

(Gongju Plant) 8-18, Bojeokdong-gil, Useong-myeon, Gongju-si, Chungcheongnam-do, 32533, Republic of Korea Design, Development and Manufacture of sterile single use surgical needles including spinal needles, epidural needles, hypodermic needles, lancet needles, umbilical cord clamp, bulk needles, cannula, sterile single use needles for injecting filler.

Tae-Chang Industrial Co., Ltd

(Gumi Plant) 127, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39378, Republic of Korea

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.









