EC Certificate Full Quality Assurance System: Certificate KR19/81826338.00

The management system of

Tae-Chang Industrial Co., Ltd

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

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 20 January 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 05 January 2004
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 209147

Multiple certificates have been issued for this scope.
The main certificate is numbered KR19/81826338.00

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

Authorised by

Digitally signed by Şarco Alexandru
Date: 2021.12.30 17:44:55 EET
Reason: MoldSign Signature
Location: Moldova

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Tae-Chang Industrial Co., Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Sterile single use spinal needles (Quincke Bevel type, Whitacre Pencil Point type);

Sterile single use Seldinger needles;

Sterile single use epidural needles;

Sterile single use hypodermic needles;

Sterile single use needles for injecting filler (Soft needle);

Sterile single use endodontic irrigation needles;

Sterile single use Insulin Syringe ;

Sterile single use Insulin Pen Needle (Insu fine, Carefine, FinePoint, DIABFINE, Medifine, TRUEplus, FINEGLIDE);

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

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

EC Certificate Full Quality Assurance System: Certificate KR19/81826338.02

The management system of

Tae-Chang Industrial Co., Ltd

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

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

Sterile single use Insulin Syringe ;
Sterile single use Insulin Pen Needle (Insu fine, Carefine, FinePoint, DIABFINE, Medifine, TRUEplus, FINEGLIDE);

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 August 2020 until 20 January 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 05 January 2004
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 209147

Multiple certificates have been issued for this scope.
The main certificate is numbered KR19/81826338.00

Authorised by

SGS Belgium NV, Notified Body 1639
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