

EC Certificate Full Quality Assurance System: Certificate KR98/13778

The management system of

Saeshin Precision Co., Ltd.

52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, 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 27 September 2016 until 6 August 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 6 August 2019

Issue 23. Certified since 6 August 1998

Certification is based on reports numbered WW/PCI 09216

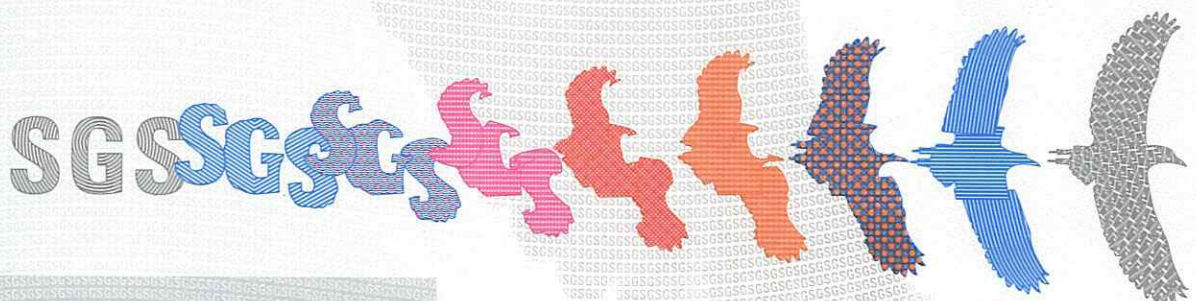
Authorised by

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Saeshin Precision Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)
for class IIa, IIb & III

Issue 23

Detailed scope

**“ACL”, “TRAUS”, “TRAUS ENDO” and “TRAUS Ultrasonic Surgical”
series contra angle & ultrasonic piezo hand-pieces for dental or
surgical bone cutting, shaving, polishing, grinding,
drilling ,endodontic treatment. (with power units)**

“ACL” series:

**Power unit (X-CUBE, SURGI CUBE, E-CUBE),
Micro motor (Forte 100α EI, CUBE 100EI, CUBE EP, CUBE EM),
Hand-pieces (AT – I, AT – II, ACL-01C, ACL(B)-01C, ACL-41I, ACL-42I,
ACL-43I, ACL-45I, ACL(B)-41I, ACL(B)-42I, ACL(B)-43I, ACL(B)-45I,
ACL(B)-51I, ACL(B)-55I, TRAUS CRB26XX, TRAUS CRB27XX, ACL(B)-
03C, ACL(B)-03F, ACL(B)-42EP, ACL(B)-42EM, TRAUS CST10XX,
TRAUS TST10XX, TRAUS CRT14XX, ACL-02C) ;**

“TRAUS” series:

**Power Unit (TRAUS XIP10, SURGI LUX, TIGER-01, TRAUS BSG10)
Micro motor (TRAUS MBP10SX, TIGER MBP 10SX, TRAUS MBP10SL,
TIGER MBP10SL, TRAUS MBP20SX),
Air motor (TRAUS MRD10NN),
Hand-pieces (AT-I,AT-II,ACL-01C,ACL(B)-01C, ACL(B)-04C, ACL-41I,
ACL-42I, ACL-43I, ACL-45I, ACL(B)-41I, ACL(B)-42I, ACL(B)-43I,
ACL(B)-45I,ACL(B)-51I, ACL(B)-55I, ACL(B)-61I, TRAUS CRB26LX,
TIGER CRB26LX, TRAUS CRB26XX, TIGER CRB26XX, TRAUS
CRB27LX, TRAUS CRB27XX, ACL(B)-03C, ACL(B)-03F, TRAUS
CST10XX, TRAUS TST10XX, TRAUS CRT14XX, TRAUS TRT12NRC,
TRAUS TRT12NOS, TRAUS TRT12NSG, TRAUS TRT12NSH);**

“TRAUS ENDO” series (“Dia-Gear” series) :

**Power unit (TRAUS MCE10XX, Dia-Gear Handpiece),
Charging station (TRAUS XEW10, Dia-Gear Charger),
Hand-pieces (ACL(B)-41EP, ACL(B)-42EP, ACL(B)-45EP, Dia-Gear
Angle);**

“TRAUS Ultrasonic Surgical” series:

**Power unit (TRAUS XUS10),
Micro Motor (TRAUS MBP10SL, TRAUS MBP10SX, TRAUS MBP20SX),
Hand-pieces (AT-I, AT-II, ACL-01C, ACL(B)-01C, ACL-41I, ACL-42I,
ACL-43I, ACL-45I, ACL(B)-41I, ACL(B)-42I, ACL(B)-43I, ACL(B)-45I,
ACL(B)-51I, ACL(B)-55I, TRAUS CRB26XX, TRAUS CRB26LX, TRAUS
CRB27XX, TRAUS CRB27LX, ACL(B)-03C, ACL(B)-03F, TRAUS
CST10XX, TRAUS TST10XX, TRAUS CRT14XX, TRAUS PEZ10XX, ACL-
02C),
Ultrasonic tips (SP-028i, SP-024i, SP-016, SP-SAW, SP-SAWL, SP-
SAWR, SP-320, SP-400, SP-610).**

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