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

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M3

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