



EC Certificate Full Quality Assurance System: Certificate KR19/81826234

The management system of

SAEYANG MICROTECH CO., LTD.

348, Seongseo-ro, Dalseo-gu, Daegu, 42697, 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 18 December 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 01 February 2008
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/07177

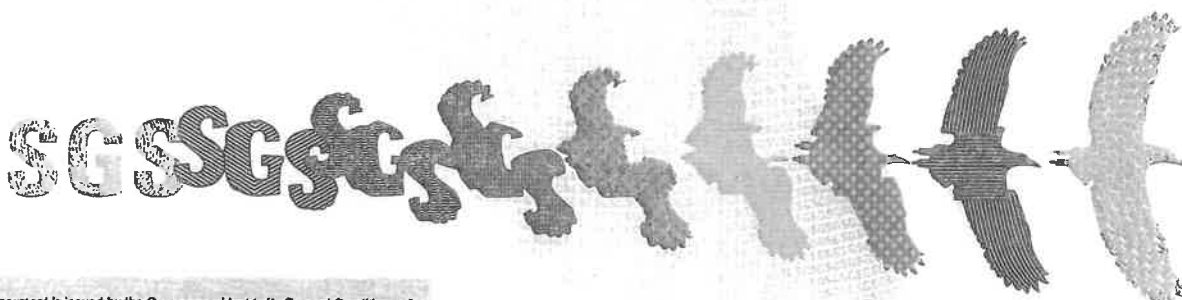
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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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SAEYANG MICROTECH CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 5

Detailed scope

Dental micromotor handpieces for intraoral use (SDE-EM24E, SDE-ES04, Ki-MTO, SGC-S101, SGC-S102, SDE-ES6, SGC-A101, SGC-A102, Ki-MT, ES-6L, SGS-S, SGS-O, SGS-R, SDE-ES100N)

Dental contra angle handpieces (Model : SP- CE, SP-RE6, SP-RE8, SP-RE10, SP-RE16, SP-RE20, SP-RE64, SP-RA4, SP-RA10, SP- RA16, SP-RA20, LP-CE, Ki-AG20, Ki-AG32, Ki-AG20L, Ki-AG20S, Ki-AG32L, Ki-AG32S)

Dental air motors (Model: SDE- AMI, SDE- AME)

Dental controllers for contra angle handpieces (Model: ENDO e class, ENDO a class, Coltene CanalPro CL2, Ki-20, Ke-40, Endo a Class(LED), Endo a Class (APX), Ki- 20 advance, SurgiMate Pro, Endo E plus, Endo Plus)

Dental air-turbine handpieces (Model: KT- 500N, KT-500NL, KT-600N, KT-600NL, KT- 500K, KT-500KL, KT-600K, KT-600KL)

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.