EC Certificate Full Quality Assurance System: Certificate KR19/81826234



The management system of

## SAEYANG MICROTECH CO., LTD.

348, Seongseo-ro, Dalseo-gu, Daegu, 704-900, 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 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. 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

Authorised by

SGS Belgium NV, Notified Body 1639

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## SAEYANG MICROTECH CO., LTD.

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

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-AG32L, 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, Endo E plus)

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