

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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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 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-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, Endo E 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.