Certificate KR08/01002

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

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of dental micromotor handpieces and controllers.
Design and manufacture of dental contra angle handpieces and dental air motors.
Design and manufacture of dental air-turbine handpieces.

This certificate is valid from 21 March 2019 until 01 February 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 January 2020
Issue 9. Certified since 01 February 2008

Authorised by

SGS United Kingdom Ltd
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HC SGS 13485 2016 0118

EC Certificate Full Quality Assurance System: KR08/01001

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 21 March 2019 until 01 February 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 January 2020
Issue 16. Certified since 01 February 2008

Certification is based on reports numbered KR/SELY-PC/07177

Authorised by

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SGS CE 02 0315 M2

SAEYANG MICROTECH CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 16

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