SAEYANG CO., LTD
(Galsan-dong), 348, Seongseo-ro, Dalseo-gu, Daegu, Korea, 42697
Tel : +82-53-582-9000 Fax : +82-53-581-9003

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Model Name: 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 controllers for contra angle handpieces ;
ENDO e class, ENDO a class, Coltene Canalpro CL2, Ki-20, Endo A Class (LED), Endo A Class (APX), Ke-40, Ki-20 Advance, Endo E plus, SurgiMate Pro, Endo Plus

Dental contra angle handpieces ;
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 ; SDE-AMI, SDE-AME

Classification : Class IIa (Annex IX Rule 9, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)

Conformity Assessment Route : Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

세양 SAEYANG
21-202106-001-hrlee

Notified Body : SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32(0)3 545-48-48 f +32(0) 545-48-49 www.sgs.com

EC Certificate Full Quality Assurance System : Certificate KR19/81826234

Standards applied : EN ISO13485:2016, EN ISO14971:2012, ISO3964:2016, ISO7494-1:2011, ISO6507-2:2005, ISO1797-1:2017, ISO9687:2015, ISO13402:1995, ISO17665-1:2006, EN ISO17664:2004, EN1041:2008, EN ISO15223-1:2016 EN60601-1:2005+AM1:2012, EN60601-1-2:2007, EN60601-1-6:2010, EN62304:2006

Manufacturers Registered Name : SAEYANG CO.,LTD.

EC Representative : Marathon Italia SRL
(VIA NUOVA SAN ROCCO, 62 80131 NAPOLI, ITALIA/ Tel.+39 081 741 31 04)

CE
1639

Signature :

Date: Oct. 21, 2024(Rev.2)

Jung Pil Shin/ CEO

DoC No. : SYMDD-DOC-001(Rev.2)

이 문서의 소유권은 ㈜세양에 있으며, 사전 동의없이 수정, 복사 및 반출 하실 수 없습니다. 21:이효령:202106-01:2025-08-05 16:23:23:192.168.0.84:HRLEE201203