EC Certificate Full Quality Assurance System: Certificate KR19/81826314

The management system of

META SYSTEMS CO., LTD.
also doing business as S-Denti Co., Ltd.

#1214-18, Sicox tower 12F, 484, Dunchon-daero, Jungwon-gu,
Seongnam-si, Gyeonggi-do, 13229, 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 19 May 2020 until 09 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19 April 2005
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 212119

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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META SYSTEMS CO., LTD.
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Directive 93/42/EEC
on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Electronic Apex Locator for measuring the working length of the tooth in endodontic treatment (Model: i-ROOT, i-ROOT 100, i-ROOT 100 mini, ROOTOR and Apex ID);

Dental Unit for endodontic treatment (model: EMS-200);

Dental Endo Motor including Contra angle handpiece (model : ES-100, EQ-M);

Dental Root Canal Obturating Materials (model: GUTTA PERCHA CARTRIDGE);

Endodontic Obturation System including Pack, Fill, Pack tip and Fill needle(model: EQ-V, Obtura Latitude and elementsIC); Sonic Powered Endo Irrigation(model: EQ-S)

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

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