



META BIOMED CO., LTD.

(Head office & Osong Factory) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, Korea)

(Cheongju Factory) 136, Mochung-ro, Seowon-gu, Cheongju-si, Chungcheongbuk-do, Korea)

Tel : + 82 - 43 - 218-1981, Fax : + 82 - 43 - 217 - 1988 Url: www.meta-biomed.com

EC Declaration of Conformity according to the Medical Devices Directive 93/42/EEC

For the following medical device :

Product : Bioceramic root canal sealer

Type Designation/Trademark : CeraSeal

Classification : Class IIa (Rule 8)

Manufacturer's Name : Meta Biomed Co., Ltd.

Manufacturer's Address : 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea

is herewith the conformity with the requirements set out in the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning Medical Devices declared, For the evaluation of the conformity with this Directive, the following standards have been applied:

EN ISO 13485:2016, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, Directive 93/42/EEC amended by Directive 2007/47/EC, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, EN 1641:2009, EN ISO 7405:2018, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, ISO 6876:2012, EN ISO 14644-1 : 2015, EN ISO 14644-2 : 2015, EN ISO 14644-3 : 2005, EN ISO 14644-4 : 2001, EN ISO 14644-5 : 2004, EN ISO 14644-6 : 2007, EN ISO 14644-7 : 2004, EN ISO 14644-8 : 2013, ISTA 1A, ASTM F1980-16

is subject to the procedure set out in Annex II (excluding sect-4) of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

GMDN Code : 36095(Endodontic filling/sealing material)

EC Certificate Number : KR19/81826259

Responsible for making this declaration is the :

■ Manufacturer: META BIOMED CO., LTD.

European Representative is:

■ Meta Biomed Europe GmbH, Wiesenstr. 35, 45473 Mulheim an der Ruhr, Germany.

■ Tel: +49-208-30991910, Fax: +49-208-30991999

Person responsible for making this declaration:

Name, Surname : Suk Song Oh

Position/Title : PRESIDENT

Place: Cheongju-si Date: January 13, 2020 (Company stamp and legal signature)