META BIOMED CO., LTD.
Osong factory): 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea
T) +82-43-216-0433 F) +82-43-217-1988
Email: info@meta-biomed.com Home Page: www.meta-biomed.com

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC

For the following medical device :

Product name :	Bioceramic root canal sealer
Brand name:	CeraSeal (detailed model names attached)
Classification :	Class IIa by Rule 8 of Annex IX, Council Directive 93/42/EEC as amended by Directive 2007/47/EC
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 14971:2019, ISO/TR 24971:2020, 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 10993-11:2018,EN 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 F1980-21, EN 62366-1:2015,IEC TR 62366-2:2016, ISO/TR 20416:2020

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
We, the manufacturer's declaration, declare and ensure with sole responsibility, that the Medical Device meet the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them

Person responsible for making this declaration:

Name, Surname : **Suk Song Oh**

Position/Title : **PRESIDENT**

Suk Song Oh

Place: **Cheongju-si** **Date:** **05 December, 2022** (Company stamp and legal signature)

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(Attachment: Model name list)

No	Brand Name	Model Name
1	CeraSeal	CeraSeal
2		CeraSeal 0.5-Pouch
3		CeraSeal 0.5-Box