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

For the following medical device :

Product Name : Light Curing Type Cavity Liner

Brand Name : Biner LC (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 13485:2012, 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, BS 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 10993-10:2010, EN ISO 10993-11:2009, ISO 9917-2:2010, ASTM F1980-21, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2001, EN ISO 14644-5:2004, KS I ISO14644-6:2017, EN ISO 14644-7:2004,EN ISO 14644-8:2013, ISTA 1A:2016, EN 62366-1:2015,IEC TR 62366-2:2016

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 : 62199 (Calcium hydroxide dental cement)

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

Suk Song Oh

META BIOMED CO., LTD.
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(Attachment: Model name list)

No	Brand Name	Model Name
1	Biner LC	Biner LC
2		Biner LC 0.5