



META BIOMED CO., LTD.

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

Chungcheongbuk-do, Korea

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

Tel : + 82 - 43 - 218-1981, Fax : + 82 - 43 - 218 - 1985 Url: www.meta-biomed.com

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device :

Product : Dual Cure Adhesive Resin Cement Set

Type Designation/Trademark : Metacem

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, EN ISO 4049:2019, EN ISO 7491:2000, ASTM F1980-16, ISTA 1A 2016, 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

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 : 35870(Dental composite resin)

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

Person responsible for making this declaration:

Name, Surname : Suk Song Oh

Position/Title : PRESIDENT

Place: Cheongju-si Date: January 17, 2020

(Company stamp and legal signature)