META BIOMED CO., LTD.
270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
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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 :	Dual-Cured Core Build-up Composite Resin
Brand Name:	NexCore (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:

Directive 93/42/EEC amended by Directive 2007/47/EC, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, EN ISO 13485:2016, FDA 21 CFR 820, EN ISO 14971:2019, ISO/TR 24971:2020, EN 1041:2008, EN ISO 15223-1:2016, EN 62366-1:2015, IEC TR 62366-2:2016, ISO/TR 20416:2020, EN 1641:2009, EN ISO 4049:2019, 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 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2022, EN ISO 14644-5:2004, EN ISO 14644-7:2004, EN ISO 14644-8:2022, EN ISO 14644-9:2022, EN ISO 14644-10:2022, ISO 14644-12:2018, EN ISO 14644-13:2017, EN ISO 14644-14:2016, EN ISO 14644-15:2017, EN ISO 14644-16:2019, EN ISO 14644-17:2021, EN ISO 14698-1:2003, EN ISO 14698-2:2003, BS EN 17141:2020, KS A 3011:2018, USP <1116>, ASTM F2847-17, ASTM G131-96(2016)e1, EN ISO 11737-1:2018/A1:2021, EN ISO/TS 17665-2:2009, Korean Pharmacopeia 12th, ASTM F1980-21, ISTA 1A:2022

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

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:** **30 November, 2023**

Suk Song Oh

(Company stamp and legal signature)

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(Attachment: Model name list)

No	Brand Name	Model Name
1	NexCore	NexCore Cartridge Tooth
2		NexCore Cartridge White
3		NexCore Cartridge Blue
4		NexCore Dual syringe Tooth
5		NexCore Dual syringe White
6		NexCore Dual syringe Blue
7		NexCore Cartridge Refill Tooth
8		NexCore Cartridge Refill White
9		NexCore Cartridge Refill Blue
10		NexCore Dual syringe Refill Tooth
11		NexCore Dual syringe Refill White
12		NexCore Dual syringe Refill Blue
13		NexCore Cartridge Refill 12.5 Tooth
14		NexCore Cartridge Refill 12.5 White
15		NexCore Cartridge Refill 12.5 Blue