META BIOMED CO., LTD.
270, Osongsaengmyeong 1-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 :	Flowable Composite Resin
Brand Name :	Nexcomp Flow (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 14644-2:2022, 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, ASTM F88/F88M-21, KS Q ISO 2859-1:2014, 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:** **November 08, 2023**

Suk Song Oh

(Company stamp and legal signature)

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(Attachment: Model name list)

No	Brand Name	Model Name
1	Nexcomp Flow	Nexcomp Flow intro Kit
2		Nexcomp Flow A1
3		Nexcomp Flow A2
4		Nexcomp Flow A3
5		Nexcomp Flow A3.5
6		Nexcomp Flow B1
7		Nexcomp Flow B2
8		Nexcomp Flow B3
9		Nexcomp Flow C2
10		Nexcomp Flow OA2
11		Nexcomp Flow OA3
12		Nexcomp Flow WT
13		Nexcomp Flow TL
14		Nexcomp Flow A4
15		Nexcomp Flow D2