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 :	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:

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 62366-1:2015, IEC TR 62366-2:2016, 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 4049:2019, 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 ISO 14644-6:2007, EN ISO 14644-7:2004, EN ISO 14644-8:2013, ISTA 1A:2016, ASTM F1980-16

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:** February 2nd, 2021 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 OA2
3		Nexcomp Flow OA3
4		Nexcomp Flow WT
5		Nexcomp Flow TL
6		Nexcomp Flow A4
7		Nexcomp Flow D2
8		Nexcomp Flow A1
9		Nexcomp Flow A2
10		Nexcomp Flow A3
11		Nexcomp Flow A3.5
12		Nexcomp Flow B1
13		Nexcomp Flow B2
14		Nexcomp Flow B3
15		Nexcomp Flow C2
16		Nexcomp Flow 0.5 A1
17		Nexcomp Flow 0.5 A2
18		Nexcomp Flow 0.5 A3
19		Nexcomp Flow 0.5 A3.5
20		Nexcomp Flow 0.5 B1
21		Nexcomp Flow 0.5 B2
22		Nexcomp Flow 0.5 B3
23		Nexcomp Flow 0.5 C2
24		Nexcomp Flow 0.5 OA2
25		Nexcomp Flow 0.5 OA3
26		Nexcomp Flow 0.5 WT
27		Nexcomp Flow 0.5 TL
28		Nexcomp Flow 0.5 A4
29		Nexcomp Flow 0.5 D2