META BIOMED CO., LTD.
Osong factory): 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea
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# 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:

MDD 93/42/EEC, EN ISO 13485:2016, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, , EN ISO 14971:2019, ISO/TR 24971:2020, EN 1041:2008, EN ISO 15223-1:2016, EN 1641:2009, EN ISO 4049:2019, EN 62366-1:2015, IEC TR 62366-2:2016, ISO/TR 20416:2020, 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, ASTM F1980-21, 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 ISO 14644-6:2007, 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

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**

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 |
| 16 | | NexCore Dual syringe Refill 2.25 Tooth |
| 17 | | NexCore Dual syringe Refill 2.25 White |
| 18 | | NexCore Dual syringe Refill 2.25 Blue |