



# Technical Information

## - Nexcomp Flow : Royal Flow -

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

2<sup>nd</sup> Factory) 136, Mochung-ro, Seowon-gu, Cheongju-si, Chungcheongbuk-do, Korea

Tel : (82-43) 218-1981 Fax : (82-43) 216-1985

META BIOMED CO., LTD.

### 1. Purpose

This specification is part of the agreement with the supplier. It is the basis and requirement for the release of orders, incoming inspections, the valuation of the supplier, complaints, and warranty claims.

**Product Name: Flowable Composite Resin**

**Brand Name: Nexcomp Flow**

**Private Label Name: Royal Flow**

### 2. General Product Introductions

#### 2.1 Product's intended use

Dental composite resin is a device intended to restore carious lesions or structural defects in teeth.

**Nexcomp Flow : Royal Flow** is indicated for Class I, II, III, IV, V restorations, Core-buildup to replace missing tooth structure, Diastema closures, Direct veneers, Composite and porcelain repairs

#### 2.2 Product's classification and regulation conformity

- a) FDA Classification – Class II, Regulation Number: 872.3690
- b) CE Classification – Class IIa, According to MDD 2007/47/EC (Annex II Rule 8)

#### 2.3 Description and Performance

**Nexcomp Flow : Royal Flow** is low viscosity, light-cured, radiopaque flowable composite resin for minimally invasive cavity preparation.

- a) Filled with 40nano sized filler for excellent polishability
- b) Flow on demand handling
- c) Excellent Radiopacity
- d) Available in 14 shades including opaque and translucent
- e) No slumping and running

#### 2.4 Mechanism Principle

As a resin-based tooth restoration material, a radical formed by photopolymerization initiates polymerization of the methacrylate-based resin monomer and is cured thereafter.



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2.5 Size

a) Sizes

| Product name | Size                                | Weight   |
|--------------|-------------------------------------|----------|
| Syringe      | Width: 135mm Inside diameter: 7.5mm | Net 3.5g |

### 3. Composition/information on ingredients

| Chemical name  | Standard            |                   |
|--|---------------------|-------------------|
| Bis-Gma[Bisphenol A Glycerolate (1glycerol/Phenol) dimethacrylate] | CAS. No. 1565-94-2  |                   |
| UDMA[Diurethane dimethacrylate]                                    | CAS. No. 72869-86-4 |                   |
| Bis-Ema[Bisphenol A ethoxylate dimethacrylate]                     | CAS. No. 41637-38-1 |                   |
| TEGDMA[Tri(ethylene glycol) dimethacrylate]                        | CAS. No. 109-16-0   |                   |
| TMPTMA[Trimethylolpropane trimethacrylate]                         | CAS. No. 3290-92-4  |                   |
| GDMA[Glycerol dimethacrylate]                                      | CAS. No. 1830-78-0  |                   |
| Camphorquinone   | CAS. No. 10373-78-1 |                   |
| Ethyl 4-(dimethylamino)benzoate                                    | CAS. No. 10287-53-3 |                   |
| BHT[2, 6-Di-Tert-Butyl-4-Methylphenol]                             | CAS. No. 128-37-0   |                   |
| 2-hydroxy-4methoxy benzephenone                                    | CAS. No. 131-57-7   |                   |
| Vanillin[4-Hydroxy-3-methoxybenzaldehyde]                          | CAS. No. 121-33-5   |                   |
| Barium aluminium boso silicate                                     | -                   |                   |
| Aerosil  | CAS. No. 68611-44-9 |                   |
| Pigment  | Titanium oxide      | FDA(21CFR73.3126) |
|  | Iron oxide yellow   | FDA(21CFR73.1200) |
|  | Iron oxide Red      | FDA(21CFR73.2250) |
|  | Iron oxide Black    | FDA(21CFR73.200)  |

\* Inorganic filler particle size: 0.04 to 0.7 $\mu$ m



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### 4. Labeling Description

4.1 LOT No.

①② ③ ④⑤ ⑥⑦⑧⑨

①②: Product Number

| Classification | Product Number |
|----------------|----------------|
| Overseas       | GE             |
| Domestic       | GD             |
| Sample         | GS             |

③: Manufacture year (0~9)

④⑤: Manufacture month (0~12)

⑥⑦⑧⑨: Order Number (1~999)

### 5. Packing Characteristics

5.1 Product package





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| Items         | Notes   |
|---------------|---|
| Weigh (g)     | <ul style="list-style-type: none"> <li>●Nexcomp Flow intro Kit</li> <li>- syringe 2g x 5ea</li> <li>-Total 10g</li> <li>●Nexcomp Flow</li> <li>-syringe 2g x 2ea</li> <li>-Total 4g</li> <li>● Nexcomp Flow 0.5</li> <li>-syringe 0.5g x 1ea</li> <li>-Total 0.5g</li> </ul>  |
| Quantity (ea) | <ul style="list-style-type: none"> <li>● Nexcomp Flow intro Kit</li> <li>- syringe 2g x 5ea, 20ea disposable tips.(A2, A3, A3.5, B2, B3)</li> <li>- syringe 2g x 5ea, 20ea disposable tips. (<b>colors in assort</b>e:A1, A2, A3, A3.5, A4, B1, B2, B3,OA2,OA3, C2, D2, WT, TL)</li> <li>● Nexcomp Flow syringe 2g x 2ea, 10ea disposable tips.</li> <li>● Nexcomp Flow 0.5 syringe 0.5g x 1ea, 3ea disposable tips.</li> <li>(A1, A2, A3, A3.5, A4, B1, B2, B3,OA2,OA3, C2, D2, WT, TL)</li> </ul> |
| Material Type | PP  |

### 5.2 Shipping Package



| Items             | Notes                                 |
|-------------------|---------------------------------------|
| Dimension (mm)    | 520(W) x 300(D) x 370(H)              |
| Gross weight (kg) | 5.58                                  |
| Material Type     | Double-wall Corrugated Fiberboard Box |



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### 6. Physical and Biological Characteristics

#### 6.1 Physical evaluation

| Test Item                     | Test Condition                                    | Result    |
|-------------------------------|---|-----------|
| Appearance                    | No impurities                                     | Propriety |
| Weight                        |   | Propriety |
| Package                       | No evidence of injury, crack and mixed impurities | Propriety |
| Sensitivity                   | Physical homogeneity                              | Propriety |
| Depth of cure                 | 1: 4.989mm<br>2: 4.988mm<br>3: 4.986mm            | Propriety |
| Flexural strength             |   | Propriety |
| Water sorption and solubility |   | Propriety |
| Shade and color stability     | No any color difference                           | Propriety |
| Radio-opacity                 |   | Propriety |

#### 6.2 Biological evaluation

| Test Item                       | Result    |
|---------------------------------|-----------|
| In Vitro Cytotoxicity           | Propriety |
| Oral Mucous Membrane Irritation | Propriety |
| Acute Systemic Toxicity         | Propriety |
| In vitro genotoxicity           | Propriety |
| Maximization sensitization test | Propriety |

### 7. Directions for Use

- ① Select the desired type and shade of Nexcomp Flow composite prior to isolating and preparing
- ② Clean the preparation with a slurry of pumice and water. Rinse and dry the preparation
- ③ Apply 37% Meta Etchant gel to available enamel / dentin for 15 seconds.  
Remove gel and rinse for 20 seconds,



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Blot dry keep moist, do not rub.

- ④ Apply Bond to the tooth - Apply a double coat of Meta P&Bond by using microbrush.

Gently air dry for 5 seconds.

Light cure for 10 seconds.

If you apply other product to saturate all internal surfaces, or bonding agent according to manufacturer's instructions

- ⑤ Place composite - Place Nexcomp Flow in increments of 2mm or less in Anterior and posterior restorations. Cure for 20 seconds in increments of 2mm.

- ⑥ Finish and Polish – After contouring composite, polish surface with finishing and polishing proximal areas.

- ⑦ Occlusion – Check lateral and centric occlusion. Adjust as necessary.

## 8. Environmental Limitation

### 8.1 Shelf Life

Use within 3 years from the manufacturing date.

### 8.2 Store

- Store at room temperature.
- Close syringe cap immediately after use.
- Avoid from directly sun light.

### HISTORY

|                                     |                        |
|-------------------------------------|------------------------|
| - Date of creation                  | : 2016.02.13           |
| - Revision number and Revision date |                        |
| * Revision number                   | : 3                    |
| * Date of last revision             | : 2019.12.31           |
| - Prepared by                       | : METABIOMED CO., LTD. |