

**SHOFU INC.**

HEAD OFFICE : 11 KAMITAKAMATSU-CHO, FUKUINE, HIGASHIYAMA-KU, KYOTO 605-0983, JAPAN  
TEL : 81-75-561-0411 FAX : 81-75-561-0412

## *Declaration of Conformity*

### *European Community Council Directive 93/42/EEC*

**Manufacturer:** SHOFU INC.  
11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 6050983,  
Japan  
**European Representative:** SHOFU DENTAL GmbH  
An der Pönt 70, 40885 Ratingen, Germany  
**Product category:** Restorative Materials, Dental, Crown/Bridge / 16723 (according to  
UMDNS-list)  
**Device Name:** SHOFU Universal Opaque  
**Product code:** Refer to appendix  
**Classification, Rule:** IIa, Rule 8

**SHOFU INC.** declares sole responsibility, that the product listed above complies with the following EC Council Directive, applicable standards and other normative documents.

The manufacturer is exclusively responsible for the declaration of conformity.

**Applicable Directive:** Medical Devices Directive 93/42/EEC as amended by 2007/47 EC  
**MDD Annex:** Annex II excluding section 4  
**Notified Body:** TÜV SÜD Product Service GmbH (Identification number is 0123)  
Ridlerstraße 65, 80339 Munich, Germany  
**Applicable Standards:** Refer to Applicable standard described in Technical File  
(CETF-99)

**EC Certificate No.:** G1 101021 0003 Rev. 01

*This declaration is valid until September 26, 2024*

Date: March 29, 2024

Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro  
General Manager of Quality Assurance Department

**SHOFU INC.**

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**99 SHOFU Universal Opaque**

| Description                              | REF  |
|------------------------------------------|------|
| SHOFU Universal Opaque OAPQUE VrO 2mL    | 2109 |
| SHOFU Universal Opaque OPAQUE A1O 2mL    | 2080 |
| SHOFU Universal Opaque OPAQUE A2O 2mL    | 2081 |
| SHOFU Universal Opaque OPAQUE A3.5O 2mL  | 2083 |
| SHOFU Universal Opaque OPAQUE A3O 2mL    | 2082 |
| SHOFU Universal Opaque OPAQUE A4O 2mL    | 2084 |
| SHOFU Universal Opaque OPAQUE B1O 2mL    | 2085 |
| SHOFU Universal Opaque OPAQUE B2O 2mL    | 2086 |
| SHOFU Universal Opaque OPAQUE B3O 2mL    | 2087 |
| SHOFU Universal Opaque OPAQUE B4O 2mL    | 2088 |
| SHOFU Universal Opaque OPAQUE BGO 2mL    | 2104 |
| SHOFU Universal Opaque OPAQUE C1O 2mL    | 2089 |
| SHOFU Universal Opaque OPAQUE C2O 2mL    | 2090 |
| SHOFU Universal Opaque OPAQUE C3O 2mL    | 2091 |
| SHOFU Universal Opaque OPAQUE C4O 2mL    | 2092 |
| SHOFU Universal Opaque OPAQUE D2O 2mL    | 2093 |
| SHOFU Universal Opaque OPAQUE D3O 2mL    | 2094 |
| SHOFU Universal Opaque OPAQUE D4O 2mL    | 2095 |
| SHOFU Universal Opaque OPAQUE GO 2mL     | 2105 |
| SHOFU Universal Opaque OPAQUE GUM-O 2mL  | 2103 |
| SHOFU Universal Opaque OPAQUE InO 2mL    | 2107 |
| SHOFU Universal Opaque OPAQUE MO 2mL     | 2106 |
| SHOFU Universal Opaque OPAQUE PO 2mL     | 2110 |
| SHOFU Universal Opaque OPAQUE R2O 2mL    | 2097 |
| SHOFU Universal Opaque OPAQUE R3.5O 2mL  | 2099 |
| SHOFU Universal Opaque OPAQUE R3O 2mL    | 2098 |
| SHOFU Universal Opaque OPAQUE rootAO 2mL | 2096 |
| SHOFU Universal Opaque OPAQUE VpO 2mL    | 2108 |
| SHOFU Universal Opaque OPAQUE W2O 2mL    | 2101 |
| SHOFU Universal Opaque OPAQUE W3O 2mL    | 2102 |
| SHOFU Universal Opaque OPAQUE WO 2mL     | 2100 |

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| Description                           | REF  |
|---------------------------------------|------|
| SHOFU Universal Opaque PRE-OPAQUE 2mL | 2111 |