



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: Burs, Dental / 10521 (according to UMDNS-list)
Device Name: OneGloss
Product code: Refer to appendix
Classification, Rule: IIa, Rule 5

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-36)

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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36 OneGloss

| Description | REF |
|----------------------------|-------|
| OneGloss PS Assorted 50PCS | 0175 |
| OneGloss PS Cup 50PCS | 0176 |
| OneGloss PS Midi 50PCS | 0177 |
| OneGloss PS IC 50PCS | 0178 |
| OneGloss Set | 0180 |
| OneGloss Cup 50PCS | 0181 |
| OneGloss Midi 50PCS | 0182 |
| OneGloss IC 50PCS | 0183 |
| OneGloss Mini-points 12PCS | 0186 |
| OneGloss M Cup 12PCS | 0187 |
| OneGloss M Midi 12PCS | 0188 |
| OneGloss M IC 12PCS | 0189 |
| OneGloss Mandrels CA | 0435 |
| OneGloss Mini Pack | N0001 |