

**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: *Procedure Kit/Trays, Dental, Restoration, Composite Resin, Light-
Cured / 16736 (according to UMDNS-list)*
Device Name: CERAMAGE
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-54)

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

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54 CERAMAGE

Description	REF
CERAMAGE OPAQUE DENTIN ODA1 4.6g(2.6mL)	1851
CERAMAGE OPAQUE DENTIN ODA2 4.6g(2.6mL)	1852
CERAMAGE OPAQUE DENTIN ODA3 4.6g(2.6mL)	1853
CERAMAGE OPAQUE DENTIN ODA3.5 4.6g(2.6mL)	1854
CERAMAGE OPAQUE DENTIN ODA4 4.6g(2.6mL)	1855
CERAMAGE OPAQUE DENTIN ODB1 4.6g(2.6mL)	1856
CERAMAGE OPAQUE DENTIN ODB2 4.6g(2.6mL)	1857
CERAMAGE OPAQUE DENTIN ODB3 4.6g(2.6mL)	1858
CERAMAGE OPAQUE DENTIN ODB4 4.6g(2.6mL)	1859
CERAMAGE OPAQUE DENTIN ODC1 4.6g(2.6mL)	1860
CERAMAGE OPAQUE DENTIN ODC2 4.6g(2.6mL)	1861
CERAMAGE OPAQUE DENTIN ODC3 4.6g(2.6mL)	1862
CERAMAGE OPAQUE DENTIN ODC4 4.6g(2.6mL)	1863
CERAMAGE OPAQUE DENTIN ODD2 4.6g(2.6mL)	1864
CERAMAGE OPAQUE DENTIN ODD3 4.6g(2.6mL)	1865
CERAMAGE OPAQUE DENTIN ODD4 4.6g(2.6mL)	1866
CERAMAGE OPAQUE DENTIN ODrootA 4.6g(2.6mL)	1867
CERAMAGE OPAQUE DENTIN ODR2 4.6g(2.6mL)	1868
CERAMAGE OPAQUE DENTIN ODR3 4.6g(2.6mL)	1869
CERAMAGE OPAQUE DENTIN ODR3.5 4.6g(2.6mL)	1870
CERAMAGE FLOWABLE COMPOSITE RESIN F-ODA3 2mL	1871
CERAMAGE CERVICAL AC1 4.6g(2.6mL)	1881
CERAMAGE CERVICAL AC2 4.6g(2.6mL)	1882
CERAMAGE CERVICAL BC1 4.6g(2.6mL)	1883
CERAMAGE CERVICAL BC2 4.6g(2.6mL)	1884
CERAMAGE CERVICAL CC1 4.6g(2.6mL)	1885
CERAMAGE CERVICAL CC2 4.6g(2.6mL)	1886
CERAMAGE CERVICAL DC1 4.6g(2.6mL)	1887
CERAMAGE CERVICAL DC2 4.6g(2.6mL)	1888
CERAMAGE INCISAL 56 4.6g(2.6mL)	1891
CERAMAGE INCISAL 57 4.6g(2.6mL)	1892

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Description	REF
CERAMAGE INCISAL 58 4.6g(2.6mL)	1893
CERAMAGE INCISAL 59 4.6g(2.6mL)	1894
CERAMAGE INCISAL 60 4.6g(2.6mL)	1895
CERAMAGE INCISAL 61 4.6g(2.6mL)	1896
CERAMAGE FLOWABLE COMPOSITE RESIN F-59 2mL	1897
CERAMAGE BODY A1B 4.6g(2.6mL)	1901
CERAMAGE BODY A2B 4.6g(2.6mL)	1902
CERAMAGE BODY A3B 4.6g(2.6mL)	1903
CERAMAGE BODY A3.5B 4.6g(2.6mL)	1904
CERAMAGE BODY A4B 4.6g(2.6mL)	1905
CERAMAGE BODY B1B 4.6g(2.6mL)	1906
CERAMAGE BODY B2B 4.6g(2.6mL)	1907
CERAMAGE BODY B3B 4.6g(2.6mL)	1908
CERAMAGE BODY B4B 4.6g(2.6mL)	1909
CERAMAGE BODY C1B 4.6g(2.6mL)	1910
CERAMAGE BODY C2B 4.6g(2.6mL)	1911
CERAMAGE BODY C3B 4.6g(2.6mL)	1912
CERAMAGE BODY C4B 4.6g(2.6mL)	1913
CERAMAGE BODY D2B 4.6g(2.6mL)	1914
CERAMAGE BODY D3B 4.6g(2.6mL)	1915
CERAMAGE BODY D4B 4.6g(2.6mL)	1916
CERAMAGE BODY rootAB 4.6g(2.6mL)	1917
CERAMAGE BODY R2B 4.6g(2.6mL)	1918
CERAMAGE BODY R3B 4.6g(2.6mL)	1919
CERAMAGE BODY R3.5B 4.6g(2.6mL)	1920
CERAMAGE FLOWABLE COMPOSITE RESIN F-A3B 2mL	1921
CERAMAGE FLOWABLE COMPOSITE RESIN F-rootAB 2mL	1922
CERAMAGE BODY W0B 4.6g(2.6mL)	1924
CERAMAGE BODY W1B 4.6g(2.6mL)	1925
CERAMAGE BODY W2B 4.6g(2.6mL)	1926
CERAMAGE BODY W3B 4.6g(2.6mL)	1927
CERAMAGE TRANSLUCENT T 4.6g(2.6mL)	1931
CERAMAGE TRANSLUCENT HVT 4.6g(2.6mL)	1932

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Description	REF
CERAMAGE TRANSLUCENT LVT 4.6g(2.6mL)	1933
CERAMAGE TRANSLUCENT T-Glass 4.6g(2.6mL)	1934
CERAMAGE TRANSLUCENT BG 4.6g(2.6mL)	1935
CERAMAGE TRANSLUCENT GT 4.6g(2.6mL)	1936
CERAMAGE TRANSLUCENT CT-A 4.6g(2.6mL)	1937
CERAMAGE TRANSLUCENT CT-B 4.6g(2.6mL)	1938
CERAMAGE TRANSLUCENT CT-R 4.6g(2.6mL)	1939
CERAMAGE TRANSLUCENT GUM-T 4.6g(2.6mL)	1940
CERAMAGE FLOWABLE COMPOSITE RESIN F-T-Glass 2mL	1941
CERAMAGE FLOWABLE COMPOSITE RESIN F-Br 2mL	1942
CERAMAGE FLOWABLE COMPOSITE RESIN F-W 2mL	1943
CERAMAGE FLOWABLE COMPOSITE RESIN F-CT-A 2mL	1944
CERAMAGE FLOWABLE COMPOSITE RESIN F-BT 2mL	1945
CERAMAGE FLOWABLE COMPOSITE RESIN F-GUM-Br 2mL	1946
CERAMAGE FLOWABLE COMPOSITE RESIN F-GUM-V 2mL	1947
CERAMAGE FLOWABLE COMPOSITE RESIN F-GUM-R 2mL	1948
CERAMAGE CONCENTRATE MI 4.6g(2.6mL)	1951
CERAMAGE CONCENTRATE WE 4.6g(2.6mL)	1952
CERAMAGE CONCENTRATE OC 4.6g(2.6mL)	1953
CERAMAGE CONCENTRATE AM-Y 4.6g(2.6mL)	1954
CERAMAGE CONCENTRATE AM-R 4.6g(2.6mL)	1955
CERAMAGE CONCENTRATE AM-V 4.6g(2.6mL)	1956
CERAMAGE CONCENTRATE MY 4.6g(2.6mL)	1957
CERAMAGE CONCENTRATE MP 4.6g(2.6mL)	1958
CERAMAGE CONCENTRATE GUM-L 4.6g(2.6mL)	1959
CERAMAGE CONCENTRATE GUM-D 4.6g(2.6mL)	1960
CERAMAGE CONCENTRATE GUM-Or 4.6g(2.6mL)	1961
CERAMAGE MODELLING LIQUID 6mL	1991
CERAMAGE GUM COLOR FULL SET with Universal Opaque	Y1804U
CERAMAGE STANDARD SET with Universal Opaque	Y1806U
CERAMAGE INTRO SET with Universal Opaque A2	Y1807U
CERAMAGE INTRO SET with Universal Opaque A3	Y1808U