

**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: Dental Materials, Restorative, Composite Resin / 16724 (according
to UMDNS-list)
Device Name: BEAUTIFIL II
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-70)

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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70 BEAUTIFIL II

Description	REF
BEAUTIFIL II A1 4.5g	1401
BEAUTIFIL II A2 4.5g	1402
BEAUTIFIL II A3 4.5g	1403
BEAUTIFIL II A3.5 4.5g	1404
BEAUTIFIL II A4 4.5g	1405
BEAUTIFIL II B1 4.5g	1408
BEAUTIFIL II B2 4.5g	1409
BEAUTIFIL II B3 4.5g	1410
BEAUTIFIL II C2 4.5g	1412
BEAUTIFIL II C3 4.5g	1413
BEAUTIFIL II Inc 4.5g	1415
BEAUTIFIL II BW 4.5g	1416
BEAUTIFIL II A2O 4.5g	1419
BEAUTIFIL II A3O 4.5g	1420
BEAUTIFIL II A1 Tips 0.25g × 20 tips	1752
BEAUTIFIL II A2 Tips 0.25g × 20 tips	1753
BEAUTIFIL II A3 Tips 0.25g × 20 tips	1754
BEAUTIFIL II A3.5 Tips 0.25g × 20 tips	1755
BEAUTIFIL II A4 Tips 0.25g × 20 tips	1756
BEAUTIFIL II B1 Tips 0.25g × 20 tips	1759
BEAUTIFIL II B2 Tips 0.25g × 20 tips	1760
BEAUTIFIL II C2 Tips 0.25g × 20 tips	1763
BEAUTIFIL II Inc Tips 0.25g × 20 tips	1766
BEAUTIFIL II BW Tips 0.25g × 20 tips	1767
BEAUTIFIL II A2O Tips 0.25g × 20 tips	1770
BEAUTIFIL II A3O Tips 0.25g × 20 tips	1771
BEAUTIFIL II 6 COLOR SET	1775
BEAUTIFIL II Tips 6 COLOR SET	1776
BEAUTIFIL II COSMETIC KIT	1777