

**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 Flow
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-63)

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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63 BEAUTIFIL Flow

Description	REF
BEAUTIFIL Flow F02 A1 2g	1431
BEAUTIFIL Flow F02 A2 2g	1432
BEAUTIFIL Flow F02 A3 2g	1433
BEAUTIFIL Flow F02 A3.5 2g	1434
BEAUTIFIL Flow F02 A4 2g	1435
BEAUTIFIL Flow F02 A3O 2g	1449
BEAUTIFIL Flow F02 G 2g	1451
BEAUTIFIL Flow F10 A1 2g	1461
BEAUTIFIL Flow F10 A2 2g	1462
BEAUTIFIL Flow F10 A3 2g	1463
BEAUTIFIL Flow F10 A3.5 2g	1464
BEAUTIFIL Flow F10 A4 2g	1465
BEAUTIFIL Flow F10 A3O 2g	1479
BEAUTIFIL Flow F10 A3T 2g	1482