



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 Plus/ BEAUTIFIL Injectable
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-83)

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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83 BEAUTIFIL Flow Plus/ BEAUTIFIL Injectable

Description	REF
BEAUTIFIL Flow Plus F00 SA0.5 2.2g	2000
BEAUTIFIL Flow Plus F00 A1 2.2g	2001
BEAUTIFIL Flow Plus F00 A2 2.2g	2002
BEAUTIFIL Flow Plus F00 A3 2.2g	2003
BEAUTIFIL Flow Plus F00 A3.5 2.2g	2004
BEAUTIFIL Flow Plus F00 A4 2.2g	2005
BEAUTIFIL Flow Plus F00 SA0.5O 2.2g	2006
BEAUTIFIL Flow Plus F00 A1O 2.2g	2007
BEAUTIFIL Flow Plus F00 A2O 2.2g	2008
BEAUTIFIL Flow Plus F00 Inc 2.2g	2010
BEAUTIFIL Flow Plus F00 BW 2.2g	2011
BEAUTIFIL Flow Plus F03 SA0.5 2.2g	2013
BEAUTIFIL Flow Plus F03 A1 2.2g	2014
BEAUTIFIL Flow Plus F03 A2 2.2g	2015
BEAUTIFIL Flow Plus F03 A3 2.2g	2016
BEAUTIFIL Flow Plus F03 A3.5 2.2g	2017
BEAUTIFIL Flow Plus F03 A4 2.2g	2018
BEAUTIFIL Flow Plus F03 A2O 2.2g	2020
BEAUTIFIL Flow Plus F03 A3O 2.2g	2021
BEAUTIFIL Flow Plus F03 Inc 2.2g	2023
BEAUTIFIL Flow Plus F03 BW 2.2g	2024
BEAUTIFIL Flow Plus F03 MI 2.2g	2026
BEAUTIFIL Flow Plus F03 CV 2.2g	2027
BEAUTIFIL Flow Plus F00 B1 2.2g	2062
BEAUTIFIL Flow Plus F00 B2 2.2g	2063
BEAUTIFIL Flow Plus F00 C2 2.2g	2064
BEAUTIFIL Flow Plus F00 D2 2.2g	2065
BEAUTIFIL Flow Plus F03 B1 2.2g	2066
BEAUTIFIL Flow Plus F03 B2 2.2g	2067
BEAUTIFIL Flow Plus F03 C2 2.2g	2068
BEAUTIFIL Flow Plus F03 D2 2.2g	2069

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Description	REF
BEAUTIFIL Flow Plus F00 SA0.5 0.21g x 20	2200
BEAUTIFIL Flow Plus F00 A1 0.21g x 20	2201
BEAUTIFIL Flow Plus F00 A2 0.21g x 20	2202
BEAUTIFIL Flow Plus F00 A3 0.21g x 20	2203
BEAUTIFIL Flow Plus F00 A3.5 0.21g x 20	2204
BEAUTIFIL Flow Plus F00 A4 0.21g x 20	2205
BEAUTIFIL Flow Plus F00 B1 0.21g x 20	2206
BEAUTIFIL Flow Plus F00 B3 0.21g x 20	2207
BEAUTIFIL Flow Plus F00 C2 0.21g x 20	2208
BEAUTIFIL Flow Plus F00 D2 0.21g x 20	2209
BEAUTIFIL Flow Plus F00 SA0.5O 0.21g x 20	2211
BEAUTIFIL Flow Plus F00 A1O 0.21g x 20	2212
BEAUTIFIL Flow Plus F00 A2O 0.21g x 20	2213
BEAUTIFIL Flow Plus F00 Inc 0.21g x 20	2215
BEAUTIFIL Flow Plus F00 BW 0.21g x 20	2216
BEAUTIFIL Flow Plus F03 SA0.5 0.21g x 20	2218
BEAUTIFIL Flow Plus F03 A1 0.21g x 20	2219
BEAUTIFIL Flow Plus F03 A2 0.21g x 20	2220
BEAUTIFIL Flow Plus F03 A3 0.21g x 20	2221
BEAUTIFIL Flow Plus F03 A3.5 0.21g x 20	2222
BEAUTIFIL Flow Plus F03 A4 0.21g x 20	2223
BEAUTIFIL Flow Plus F03 B1 0.21g x 20	2224
BEAUTIFIL Flow Plus F03 B2 0.21g x 20	2225
BEAUTIFIL Flow Plus F03 C2 0.21g x 20	2226
BEAUTIFIL Flow Plus F03 D2 0.21g x 20	2227
BEAUTIFIL Flow Plus F03 A2O 0.21g x 20	2229
BEAUTIFIL Flow Plus F03 A3O 0.21g x 20	2230
BEAUTIFIL Flow Plus F03 Inc 0.21g x 20	2232
BEAUTIFIL Flow Plus F03 BW 0.21g x 20	2233
BEAUTIFIL Flow Plus F03 MI 0.21g x 20	2235
BEAUTIFIL Flow Plus F03 CV 0.21g x 20	2236