

**SHOFU INC.**

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Declaration of Conformity

Manufacturer: SHOFU INC.
11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 6050983, Japan

SRN Number: JP-MF-000015205

European Representative: SHOFU DENTAL GmbH
An der Pönt 70, 40885 Ratingen, Germany

SRN Number: DE-AR-000004951

Device Name: BEAUTIFIL II

Product Category: Non-active dental implants and dental materials / MDN 1103
DENTAL CONSERVATION COMPOSITES / Q01010103 (according to EMDN list)

Basic UDI-DI: 45481620077T

Product Code: Refer to appendix

Classification, Rule: IIa, Rule 8, 1st indent

SHOFU INC. declares sole responsibility that the product listed above complies with the following EU Regulation, applicable standards and other normative documents.
The manufacturer is exclusively responsible for the declaration of conformity.

Applicable Regulation: Medical Devices Regulation (EU) 2017/745

MDR Annex: Annex IX Chapters I and III (Class IIa)

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 Documentation (TED-070)

Common Specifications: Not applicable specifications

EU Certificate No.: G10 101021 0004 Rev. 00

This declaration is valid until 2027-08-24

Date: 2024-06-07

Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department



Device listing

(As of 2024-06-07)

Basic UDI-DI: 45481620077T

UDI-DI	REF	Product name	Product code
04548162338679	YE1779	BEAUTIFIL II 6 Color Value Pack	C329
04548162304445	YE1401	BEAUTIFIL II 4.5g A1 Syringe 1pc	C330A1
04548162304452	YE1402	BEAUTIFIL II 4.5g A2 Syringe 1pc	C330A2
04548162304469	YE1419	BEAUTIFIL II 4.5g A2O Syringe 1pc	C330A2O
04548162304476	YE1403	BEAUTIFIL II 4.5g A3 Syringe 1pc	C330A3
04548162304483	YE1404	BEAUTIFIL II 4.5g A3.5 Syringe 1pc	C330A35
04548162304490	YE1420	BEAUTIFIL II 4.5g A3O Syringe 1pc	C330A3O
04548162304506	YE1405	BEAUTIFIL II 4.5g A4 Syringe 1pc	C330A4
04548162304513	YE1408	BEAUTIFIL II 4.5g B1 Syringe 1pc	C330B1
04548162304520	YE1409	BEAUTIFIL II 4.5g B2 Syringe 1pc	C330B2
04548162304537	YE1410	BEAUTIFIL II 4.5g B3 Syringe 1pc	C330B3
04548162304544	YE1416	BEAUTIFIL II 4.5g BW Syringe 1pc	C330BW
04548162304551	YE1412	BEAUTIFIL II 4.5g C2 Syringe 1pc	C330C2
04548162304568	YE1413	BEAUTIFIL II 4.5g C3 Syringe 1pc	C330C3
04548162304575	YE1415	BEAUTIFIL II 4.5g Inc Syringe 1pc	C330INC
04548162304612	YE1752	BEAUTIFIL II 0.25g A1 Tips 20pcs	C334A1
04548162304629	YE1753	BEAUTIFIL II 0.25g A2 Tips 20pcs	C334A2
04548162304636	YE1770	BEAUTIFIL II 0.25g A2O Tips 20pcs	C334A2O
04548162304643	YE1754	BEAUTIFIL II 0.25g A3 Tips 20pcs	C334A3
04548162304650	YE1755	BEAUTIFIL II 0.25g A3.5 Tips 20pcs	C334A35
04548162304667	YE1771	BEAUTIFIL II 0.25g A3O Tips 20pcs	C334A3O
04548162304674	YE1756	BEAUTIFIL II 0.25g A4 Tips 20pcs	C334A4
04548162304681	YE1759	BEAUTIFIL II 0.25g B1 Tips 20pcs	C334B1
04548162304698	YE1760	BEAUTIFIL II 0.25g B2 Tips 20pcs	C334B2
04548162304704	YE1767	BEAUTIFIL II 0.25g BW Tips 20pcs	C334BW
04548162304711	YE1763	BEAUTIFIL II 0.25g C2 Tips 20pcs	C334C2
04548162304728	YE1766	BEAUTIFIL II 0.25g Inc Tips 20pcs	C334INC