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:	*Tooth paste* *(according to UMDNS-list)*
Device Name:	*Pressage*
Classification, Rule:	*Class I, Rule 5*

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
Applicable Standards:	Refer to Applicable starndard described in Technical File (CETF-51)

The earliest date of manufacture of the first device putted on the market under the Declaration of Conformity is 2019/03/30

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Tooth paste* *(according to UMDNS-list)*
Device Name:	*Merssage*
Classification, Rule:	*Class I, Rule 5*

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
Applicable Standards:	Refer to Applicable starndard described in Technical File (CETF-50)

The earliest date of manufacture of the first device putted on the market under the Declaration of Conformity is 2019/03/30

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Adhesives / 10034* *(according to UMDNS-list)*
Device Name:	*SHOFU Universal Primer*
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 starndard described in Technical File (CETF-122)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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 UP*
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 starndard described in Technical File (CETF-105)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Restorative Materials, Dental, Crown/Bridge / 16723* *(according to UMDNS-list)*
Device Name:	*SHOFU Universal Opaque*
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 starndard described in Technical File (CETF-99)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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 starndard described in Technical File (CETF-83)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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 starndard described in Technical File (CETF-70)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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 starndard described in Technical File (CETF-63)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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, Repair, Porcelain / 16738* *(according to UMDNS-list)*
Device Name:	*CERARESIN BOND*
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 starndard described in Technical File (CETF-55)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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 starndard described in Technical File (CETF-54)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Burs, Dental / 10521* *(according to UMDNS-list)*
Device Name:	*OneGloss*
Product code:	Refer to appendix
Classification, Rule:	*IIa, Rule 5*

***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 starndard described in Technical File (CETF-36)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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, Cement, Glass Ionomer / 16704* *(according to UMDNS-list)*
Device Name:	*GlasIonomer Cement CX-Plus*
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 starndard described in Technical File (CETF-29)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Burs, Dental / 10521* *(according to UMDNS-list)*
Device Name:	*SHOFU ABRASIVE KITS (Composite Polishing Kit, Composite Technique Kit, Enamel Adjustment Kit, Porcelain Veneer Kit, Super-Snap X-TREME Technique Kit, Super-Snap Rainbow Technique Kit, Super-Snap Mini-Kit,GIC Polishing Kit, Super-Snap X-TREME Technique Mini-Kit, CeraMaster Finishing & Polishing Kit, CompoMaster Finishing & Polishing Kit, ZiLMaster Adjustment Kit, Super-Snap X-TREME Disk Kit, Super-Snap Disk Kit)*
Product code:	Refer to appendix
Classification, Rule:	*IIa, Rule 5*

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 starndard described in Technical File (CETF-12)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*Burs, Dental / 10521* *(according to UMDNS-list)*
Device Name:	*Super-Snap*
Product code:	Refer to appendix
Classification, Rule:	*IIa, Rule 5*

***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 starndard described in Technical File (CETF-5)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department

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:	*SOLIDEX*
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 starndard described in Technical File (CETF-1)

EC Certificate No.: G1 101021 0003 Rev. 01

This declaration is valid until March 29, 2024

Date: September 7, 2020
Place: at SHOFU INC., Kyoto, Japan

Hisaaki Tachidokoro
General Manager of Quality Assurance Department