



**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:** *Ila, 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-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

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